

MEDIMMUNE INC /DE  
Form 10-K  
March 09, 2004

Use these links to rapidly review the document  
[MEDIMMUNE, INC. FORM 10-K TABLE OF CONTENTS](#)

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2003  
Commission File Number: 000-19131**

---

**MEDIMMUNE, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**52-1555759**

(I.R.S. Employer Identification No.)

**35 West Watkins Mill Road  
Gaithersburg, Maryland 20878**

(Address of principal executive office)  
(Zip Code)

Registrant's telephone number, including area code: **(301) 417-0770**

Securities Registered pursuant to Section 12(b) of the Act: **None**

Securities Registered pursuant to Section 12(g) of the Act:

**Common Stock, \$.01 par value**

(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K .

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes  No

Aggregate market value of the 250,941,192 shares of voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price on June 30, 2003, was \$9.1 billion. Common Stock outstanding as of February 29, 2004: 248,227,030 shares.

**Documents Incorporated by Reference:**

# Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

Portions of the registrant's definitive proxy statement for the annual meeting of stockholders to be held May 20, 2004 (Part III).

---

---

## MEDIMMUNE, INC. FORM 10-K TABLE OF CONTENTS

### PART I

- Item 1. Business
- Item 2. Properties
- Item 3. Legal Proceedings
- Item 4. Submission of Matters to a Vote of Security Holders

### PART II

- Item 5. Market for MedImmune, Inc.'s Common Stock and Related Shareholder Matters
- Item 6. Selected Consolidated Financial Data
- Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations
- Item 7A. Quantitative and Qualitative Disclosures about Market Risk
- Item 8. Consolidated Financial Statements and Supplementary Data
  - Report of Independent Auditors
  - Report of Management
- Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure
- Item 9A. Controls and Procedures

### PART III

- Item 10. Directors and Executive Officers of MedImmune, Inc.
- Item 11. Executive Compensation
- Item 12. Security Ownership Certain Beneficial Owners and Management
- Item 13. Certain Relationships and Related Transactions
- Item 14. Principal Accounting Fees and Services

### PART IV

- ITEM 15. Exhibits, Financial Statement Schedule, and Reports on Form 8-K

### SIGNATURES

#### Schedule I

#### Exhibit Index

Exhibits (Attached to this Report on Form 10-K)

Synagis, CytoGam, Ethyol, RespiGam, NeuTrexin and Vitaxin are registered trademarks of the Company. Numax and FluMist are trademarks of the Company.

---

## FORWARD LOOKING STATEMENTS

*The statements in this annual report that are not descriptions of historical facts may be forward-looking statements. Those statements involve substantial risks and uncertainties. You can identify those statements by the fact that they contain words such as "anticipate," "believe," "estimate," "expect," "intend," "project" or other terms of similar meaning. Those statements reflect management's current beliefs, but are based on numerous assumptions, which MedImmune cannot control and that may not develop as MedImmune expects. Consequently, actual results may differ materially from those projected in the forward-looking statements. Among the factors that could cause actual results to differ materially are the risks, uncertainties and other matters discussed below under "Risk Factors" and elsewhere in this report. MedImmune cautions that RSV disease and influenza occur primarily during the winter months; MedImmune believes its operating results will reflect that seasonality for the foreseeable future. MedImmune is also developing several products for potential future marketing. There can be no assurance that such development efforts will succeed, that such products will receive required regulatory clearance or that, even if such regulatory clearance is received, such products will ultimately achieve commercial success. Unless otherwise indicated, the information in this annual report is as of December 31, 2003. This annual report will not be updated as a result of new information or future events.*

---

**PART I**

**ITEM 1. BUSINESS**

MedImmune, Inc. (together with its subsidiaries, "MedImmune" or the "Company") is a biotechnology company that uses advances in biological sciences to discover, develop, manufacture and commercialize products that treat or prevent infectious diseases, immune system disorders and cancer. The Company's core competencies are in the areas of monoclonal antibodies and vaccines.

Founded in 1988, MedImmune is headquartered in Gaithersburg, Maryland and has three primary operating subsidiaries: MedImmune Oncology, Inc., MedImmune Vaccines, Inc. and MedImmune Ventures, Inc. The Company promotes three main products: Synagis® (palivizumab) and FluMist (Influenza Virus Vaccine Live, Intranasal) to prevent two common respiratory infectious diseases; and Ethyol® (amifostine) to reduce undesired side effects of certain anti-cancer chemo- and radiotherapies.

MedImmune operates five facilities in the United States and Europe to manufacture one or more components of each of these products and promotes these products in the U.S. through its own sales and marketing organization. In addition, the Company has entered into agreements with other companies to manufacture certain components of these products, promote these products outside of the U.S. and support the Company's promotional efforts in the U.S.

MedImmune also has clinical, research and development staff in the U.S., through which it is developing a pipeline of product candidates for potential commercialization. In addition to its internal efforts, the Company has established clinical, research, development and commercialization collaborations with other companies and organizations.

**Products**

**Synagis**

Synagis is a humanized monoclonal antibody approved for marketing in 1998 by the U.S. Food and Drug Administration (the "FDA") for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus ("RSV") in pediatric patients at high risk of acquiring RSV disease, such as premature infants. RSV is the most common cause of lower respiratory tract infections in infants and children worldwide. Healthy children and individuals with adequate immune systems often acquire a benign chest cold when infected with RSV. In contrast, high-risk infants and children with chronic lung disease, also known as bronchopulmonary dysplasia ("BPD"), are at increased risk for acquiring severe RSV disease (pneumonia and bronchiolitis), often requiring hospitalization. In 2003, based on additional clinical trial data, the FDA approved expansion of the definition of high-risk patients to include children with certain heart diseases present at birth (hemodynamically significant congenital heart disease ("CHD")).

Synagis is most commonly administered by intramuscular injection once per month during anticipated periods of RSV prevalence in the community. In the northern hemisphere, the RSV season typically commences in October and lasts through April or May. As such, the sales of this product reflect this seasonality and occur primarily in the first and fourth quarters of the calendar year. In the U.S., Synagis is co-promoted by MedImmune and by the Ross Products Division of Abbott Laboratories ("Abbott").

Outside the U.S., the International Division of Abbott ("AI") has the exclusive right to distribute Synagis. As of February 29, 2004, 49 countries outside the U.S. had approved Synagis for marketing. In July 2003, AI announced that the European Agency for the Evaluation of Medicinal Products had granted a positive opinion for the use of Synagis in young children born with CHD to prevent lower respiratory tract infection caused by RSV.

---

In 2003, 2002 and 2001, the Company reported \$849 million, \$672 million and \$518 million, respectively in worldwide net revenues from Synagis representing 86%, 85% and 89% of the Company's total net revenues in 2003, 2002 and 2001, respectively.

**Ethyol**

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

Ethyol is used to prevent certain unwanted side effects of specific types of chemo- and radiotherapies that are used to treat cancer. In the U.S., Ethyol was initially approved by the FDA in 1995 to reduce the cumulative renal (kidney) toxicity associated with repeated administration of cisplatin (a common chemotherapy agent) to patients with advanced ovarian cancer.

In 1996, the FDA approved the Company's supplemental new drug application under the FDA's Accelerated Approval Regulations to include treatment of patients with non-small cell lung cancer ("NSCLC"). Products approved under the Accelerated Approval Regulations require further adequate and well-controlled studies to verify and describe clinical benefit. The Company completed a post-licensure clinical trial in 2001 showing that Ethyol protected against cisplatin-induced renal toxicity. The Company believed this trial would fulfill the Accelerated Approval requirement and submitted its data to the FDA for review in 2002. Early in 2003, the Company met with the FDA to discuss the their belief that the study did not meet the Accelerated Approval requirement, as well as the FDA's request that another trial be conducted. The Company is currently discussing an appropriate study design with the FDA. If no agreement can be reached on the design of such a study, there can be no assurances that the FDA will not withdraw approval of Ethyol for the NSCLC indication. MedImmune does not believe that the withdrawal of this indication, should the FDA decide to do so, will meaningfully impact the market potential for Ethyol.

In 1999, the FDA also approved the use of Ethyol for the reduction of the incidence of moderate-to-severe dry mouth (xerostomia) in patients undergoing post-operative radiation treatment for head and neck cancer, when a significant portion of the parotid glands are located in the radiation treatment field. Xerostomia, both acute and chronic, is a debilitating condition in which saliva production is reduced due to damage caused to the salivary glands by therapeutic radiation. Patients with xerostomia are at increased risk of oral infection, dental cavities and loss of teeth and often have difficulty chewing, swallowing and speaking.

Since 2001, MedImmune has been the sole marketer of Ethyol in the U.S. Prior to this date, Ethyol was co-promoted by MedImmune and ALZA Corporation ("ALZA"). Outside the U.S., the Company has various distribution and marketing arrangements for Ethyol, primarily with affiliates of Schering-Plough Corporation ("Schering"). This product has been approved for marketing in 60 countries worldwide, including the United States.

In 2003, 2002 and 2001, MedImmune reported worldwide net revenues for Ethyol of \$100 million, \$81 million and \$20 million, respectively, which represented nine percent, ten percent, and three percent of the Company's total net revenues in each of these three years.

### **FluMist**

FluMist is a vaccine approved for marketing in June 2003 by the FDA for the prevention of disease caused by influenza A and B viruses in healthy children and adolescents, 5-17 years of age, and healthy adults, 18-49 years of age. FluMist is delivered as a nasal mist and is a live, attenuated vaccine, meaning that it uses live viruses that have been modified and weakened to stimulate the immune system to prevent the flu. Each year in the U.S., the influenza virus infects an estimated 17 million to 50 million people, many of whom are otherwise healthy children and adults. In September 2003, the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention ("CDC") issued a Supplemental Recommendation for the use of live, attenuated influenza vaccine to its annual Recommendations for the Prevention and Control of Influenza.

3

---

FluMist is the subject of a collaborative arrangement with Wyeth. FluMist is manufactured by MedImmune, distributed in the U.S. exclusively by Wyeth and co-promoted in the U.S. by MedImmune and Wyeth. Outside of the U.S., Wyeth has exclusive rights to FluMist worldwide, excluding Australia, New Zealand, North Korea, South Korea, and some South Pacific countries.

MedImmune's FluMist-associated revenues are dependent on payments from Wyeth for: transfer of product to Wyeth; achievement of certain milestones; royalties on net sales; and reimbursement for certain expenses. Vaccination against the influenza virus in the northern hemisphere typically commences in October and may last through January. Once the Company has gained some historical experience with respect to the impact of returns and discounting, the timing of when the Company reports revenues attributable to FluMist is expected to reflect this seasonality.

In 2003, MedImmune reported \$46 million in net revenues for FluMist, or about four percent of the company's total revenues. This amount was derived solely from milestone and reimbursement payments from Wyeth. The Company did not record any sales-related revenue in 2003 due to the uncertainty associated with returns and discounts in the vaccine's launch season.

### **Other Products**

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

The Company also markets the following three additional products for which it reported a total of \$43 million, \$38 million, and \$43 million in worldwide net product sales in 2003, 2002 and 2001, respectively. These amounts represent four percent of the Company's total reported net revenues in 2003 and 2002 and seven percent of the Company's total reported net revenues in 2001.

**CytoGam® (cytomegalovirus immune globulin intravenous (human))** an intravenous immune globulin product enriched in antibodies against cytomegalovirus ("CMV"), a herpesvirus, marketed to prevent CMV disease associated with kidney, lung, liver, pancreas or heart transplantation.

**NeuTrexin® (trimetrexate glucuronate for injection)** a lipid-soluble analog of methotrexate, approved for use with concurrent leucovorin administration as an alternative therapy for the treatment of moderate-to-severe *Pneumocystis carinii* pneumonia in immunocompromised patients, such as AIDS patients.

**RespiGam® (respiratory syncytial virus immune globulin intravenous (human))** an intravenous immune globulin enriched in neutralizing antibodies against RSV, indicated for the prevention of serious RSV disease in children less than 24 months of age with BPD or a history of premature birth (i.e., born at 35 weeks or less gestation). RespiGam was the Company's first anti-RSV product and has largely been replaced by Synagis in the marketplace. The manufacturer and license holder for RespiGam is no longer producing this product and has provided the FDA with notice of intent to withdraw the Biologics License Application for this product.

### *Product Candidates*

A large portion of MedImmune's operating expenses are related to the research and development of its product candidates. Research and development expenses were \$156 million in 2003, \$148 million in 2002 and \$83 million in 2001. MedImmune currently focuses its research and development efforts in the therapeutic areas of infectious diseases, immunology and oncology. The Company also continues to work on feasibility studies in a number of other areas. Any of these programs could become more significant to the Company in the future, but there can be no assurance that any of the new programs under review will generate viable marketable products. As such, the Company continually evaluates all product candidates and may, from time to time, discontinue the development of any given program and focus its attention and resources elsewhere. The Company may choose to address new opportunities for future growth in a number of ways including, but not limited to, internal discovery and development of

4

---

new products, in-licensing of products and technologies, and/or acquisition of companies with products and/or technologies. Any of these activities may require substantial research and development efforts and expenditure of significant amounts of capital.

The following table summarizes the Company's current product candidate programs and each is described in greater detail below:

<b>Infectious Disease</b>	<b>Immunology</b>	<b>Oncology</b>
CAIV-T (liquid)	Vitaxin®	Ethyol
Synagis (liquid)	Anti-IL-9 antibody	HPV
Numax	HMGB-1	Vitaxin
Epstein-Barr Virus vaccine		Siplizumab
<i>S. pneumoniae</i> vaccine		MT-103
hMPV antibody and vaccine		EphA2

**Infectious Disease**

**Immunology**

**Oncology**

PIV-3/RSV/hMPV combination vaccine

PCDGF  
EphA4

**Infectious Disease**

**CAIV-T (cold adapted influenza virus vaccine trivalent, liquid)** CAIV-T is being developed under collaborative agreements between Wyeth and MedImmune as a liquid, refrigerator-stable version of the trivalent, live, attenuated, cold-adapted influenza virus vaccine. Liquid CAIV-T may have the potential to replace the frozen formulation of MedImmune's influenza vaccine since frozen vaccines pose additional distribution and commercial challenges. Wyeth has been conducting late-stage clinical trials with CAIV-T and has begun collecting and evaluating that data.

**Synagis (liquid)** MedImmune is developing a liquid formulation of Synagis to improve the product's ease-of-use. Currently, Synagis is a lyophilized (freeze dried) product that requires a waiting period following reconstitution with water prior to use. In 2003, MedImmune completed clinical and biochemical comparability studies and began preparing to submit a supplement to its biologics license application for Synagis to the FDA for this liquid formulation.

**Numax** MedImmune has been developing a third generation anti-RSV antibody product, Numax that appears to be more potent in preclinical studies than Synagis. In 2003, MedImmune submitted an Investigational New Drug ("IND") application to the FDA and initiated a Phase 1 clinical program for Numax.

**Epstein-Barr Virus Subunit Vaccine** MedImmune has rights to a vaccine against certain subunits of Epstein-Barr virus ("EBV"), a herpesvirus that is the leading cause of infectious mononucleosis. This vaccine is based upon the major envelope glycoprotein that mediates viral absorption and penetration, and is a major target for the production of neutralizing antibodies stimulated by natural EBV infection. The vaccine is being developed under a collaboration with GlaxoSmithKline ("GSK"). Data from a 2002 GSK study in Europe showed that the formulations were both well tolerated and highly immunogenic. Although the study was not specifically designed to assess vaccine efficacy, none of the volunteers developed symptoms of infectious mononucleosis during the study period. A Phase 2 feasibility trial, initiated and fully enrolled in 2002 by GSK, continued in 2003.

**Streptococcus pneumoniae Vaccine** In 2000, MedImmune granted a worldwide exclusive license to *Streptococcus pneumoniae* vaccine to GSK. *Streptococcus pneumoniae* is a major cause of pneumonia, middle-ear infections and meningitis worldwide, especially in the very young and

elderly. During 2003, GSK continued its preclinical research efforts with vaccine candidates and initiated a Phase 1 clinical study.

**Human Metapneumovirus Program** The human metapneumovirus ("hMPV") is a newly identified respiratory virus with a high incidence of infection in young children under the age of five. Early epidemiological studies indicate that outbreaks of hMPV occur on a seasonal basis, with clinical symptoms that are largely similar to RSV, ranging from mild respiratory problems to severe cough, bronchiolitis, and pneumonia, with the very youngest children often requiring hospitalization and mechanical ventilation. In 2003, MedImmune continued its epidemiological study of hMPV and conducted preclinical tests assessing the potential to develop antibodies and/or vaccines to prevent or treat infection by this new virus.

**Parainfluenza Virus Type 3/RSV/hMPV Combination Vaccine** Substantial preclinical research has been conducted toward the goal of combining previously independent vaccine programs against parainfluenza virus type 3 ("PIV-3") and RSV. The Company has also begun efforts to include hMPV in a potential combined vaccine program, which, if successful, could be used to prevent disease against some combination of these three viruses. Additional preclinical research and process development to further evaluate the safety and efficacy of live, attenuated intranasal vaccine candidates targeting

combinations of PIV-3 and RSV or PIV-3 and hMPV were conducted during 2003.

## Immunology

**Vitaxin** Vitaxin is a monoclonal antibody in development for both immunological disorders and certain types of cancer. Vitaxin targets alpha-v beta-3, an integrin, which is a particular receptor protein, expressed on a number of cell types, including those found in newly forming blood vessels, certain white blood cells and bone cells, and on the surface of certain types of solid tumors. In 2003, the Company completed its initial Phase 1 development with Vitaxin and initiated two Phase 2 trials in autoimmune diseases (rheumatoid arthritis and psoriasis) to assess the antibody's ability to be used safely and effectively in treating patients with either of these diseases.

**Anti-IL-9 Antibody** IL-9 is a naturally occurring cytokine implicated in the pathogenesis of asthma and may contribute to other types of chronic obstructive pulmonary disease and cystic fibrosis. During 2003, MedImmune selected its lead candidate molecule and submitted an IND to the FDA.

**High Mobility Group Box Chromosomal Protein 1 (HMGB-1)** HMGB-1 is a late-acting cytokine believed to be involved in the tissue damage associated with a range of inflammatory illnesses, such as rheumatoid arthritis, sepsis and acute lung injury. Preclinical studies to date have suggested that blocking HMGB-1 may help protect against injury associated with many chronic and acute inflammatory diseases, and may reduce sepsis-related deaths. In 2003, MedImmune entered into an agreement with Critical Therapeutics, Inc. to co-develop biological products targeting HMGB-1 to treat severe inflammatory diseases. The companies plan to focus on developing drug products with the potential to block HMGB-1 that, if successful, could help reduce the injury and death associated with severe inflammatory diseases and infections.

## Oncology

**Ethiol** During 2003, MedImmune began enrollment in two new clinical studies to possibly expand the use of Ethiol in new indications. The first trial is a Phase 2 study using subcutaneous administration of Ethiol to evaluate its ability to reduce the incidence or severity of radiation-induced esophagitis and pneumonitis in patients with NSCLC. The second new trial is a Phase 1/2 clinical study evaluating Ethiol's effectiveness in preventing toxicity associated with

6

---

dose escalation of chemotherapy in elderly patients with newly diagnosed, previously untreated acute myelogenous leukemia, the most common type of leukemia reported in adults.

**Human Papillomavirus Vaccine** MedImmune and GSK are developing a vaccine against human papillomavirus ("HPV") to prevent cervical cancer under a research collaboration. There are over 75 different types of HPV associated with a variety of clinical disorders, ranging from benign lesions to potentially lethal cancers. Two strains of HPV (HPV-16 and -18) are generally believed to cause most cervical cancers. MedImmune and GSK's vaccine candidate uses virus-like particle technology to produce a structurally identical, non-infectious form of the virus. In April 2003, preliminary data from a Phase 2 HPV vaccine clinical trial was presented by GSK at the European Research Organization on Genital Infection and Neoplasia EUROGIN Meeting in Paris. Final data were presented on the HPV vaccine by GSK in February 2004 at The International Papillomavirus Conference. We expect GSK to publish additional data on this vaccine in the near future.

**Vitaxin** As described above, the Company has been developing Vitaxin for use in both cancer and immunological disorders. Vitaxin functions by blocking the function of alpha-v beta-3 integrin, which is frequently found on newly-forming blood vessels and certain tumor cells (for example, melanoma, prostate cancer, and tumors with bone metastases). MedImmune initiated two Phase 2 trials during 2003 in patients diagnosed with melanoma and prostate cancer.

**Siplizumab** Siplizumab is a humanized monoclonal antibody that targets CD2, a molecule expressed on certain white blood cells, and appears to have the effect of depleting T cells and Natural Killer ("NK") cells. These properties suggest that siplizumab could provide a treatment for patients with T-cell lymphoproliferative disorders. Animal studies of T-cell leukemia have indicated that siplizumab can increase survival. In 2003, MedImmune filed an IND for siplizumab with the intention of initiating a Phase 1 trial to examine the clinical safety of siplizumab in individuals with CD2-positive lymphoproliferative disorders and to determine the maximum tolerated dose of the antibody in these patients.

**MT-103** In June 2003, MedImmune licensed the North American rights from Micromet AG to MT-103, a bi-specific T-cell engager (BiTE ) molecule that binds to B-cell lymphomas that express the CD19 surface molecule. With its second binding arm, MT-103 recruits and activates T-cells to kill the cancerous B-cells. MedImmune is also evaluating the broader application of Micromet's BiTE technology to other targets of interest.

**EphA2** EphA2 is normally expressed at very low levels on normal epithelial cells, but many different cancers significantly over express EphA2, including metastatic melanoma, breast, prostate, colon, lung, ovarian and esophageal carcinomas. Further, when over-expressed, EphA2 appears to promote metastases. Based on its studies to date, MedImmune believes that antibodies targeting EphA2 in animal models may selectively inhibit the growth and survival of malignant cells, but do not alter the function or survival of corresponding normal cells. In 2003, MedImmune continued its preclinical testing of EphA2 antibodies.

**PCDGF** PC-cell-derived growth factor ("PCDGF") is over expressed by many different types of cancer, for example breast cancers that have become refractory to conventional hormone therapies. Preclinical studies indicate that inhibition of PCDGF expression decreases the growth and survival of aggressive, hormone-refractory breast cancer cells. Additionally, studies by MedImmune investigators and others have linked high levels of PCDGF with ovarian and prostate carcinomas as well as multiple myeloma. In 2003, the Company continued its preclinical investigation potentially therapeutic antibodies.

**EphA4** In 2003, MedImmune identified EphA4 as a potential new target on certain cancer cells. Preclinical studies indicate that high levels of EphA4 are found on many different cancers,

7

---

including breast and pancreatic carcinomas and that targeted intervention against EphA4 may decrease the proliferation and metastatic behavior of these malignant cells.

### ***Collaborations, Alliances and Investments***

To build, advance and promote its product portfolio, MedImmune seeks to augment its own internal programs and capabilities with collaborative projects with a number of outside partners. For its marketed products, the Company has established a number of license agreements, co-promotion arrangements, manufacturing, supply and co-development alliances with pharmaceutical and other biotechnology companies, academic institutions and government laboratories to which the Company currently pays royalties. For more information on these collaborations, please see Note 15, "Collaborative Arrangements" to MedImmune's Consolidated Financial Statements. Similarly, for product candidates now in development, the Company has secured licenses to certain intellectual property and entered into strategic alliances with outside parties for various aspects of research, development, manufacturing and commercialization to which the Company will owe future royalties if the product candidates are licensed and commercialized. These entities and outside parties are described in the preceding "Product Candidates" section.

The Company also believes that investing in early stage biotechnology companies allows the Company to benefit from other innovations in the industry. Accordingly, the Company has established a wholly owned venture capital subsidiary, MedImmune Ventures, Inc., that makes minority investments in biotechnology companies that the Company believes have promising technology. Occasionally, the Company will make these investments in connection with strategic alliances as it did previously with Genaera Corporation and A&G Pharmaceuticals, Inc. and in 2003 with Micromet AG and Critical Therapeutics, Inc. In 2003, the Company also invested in: Tercica, Inc., a biopharmaceutical company focused on the development and commercialization of therapies to treat disorders of the endocrine system, including human growth and diabetes; Applied Genetic Technologies Corporation, a drug research company developing novel human therapeutics, principally a gene therapy treatment for Alpha-One Antitrypsin Deficiency (A<sub>1</sub>AD), a form of emphysema; and VaxInnate Corporation, an early stage company engaged in the development of immunostimulating agents, including vaccines and immunosuppressive agents. In connection with such investments, the Company will sometimes be entitled to appoint a member of the board of directors of these portfolio companies, and in such cases, a Company employee is generally appointed to serve in that role.



**Marketing and Sales**

The Company has developed a sales and marketing organization that it believes is responsive to the increased importance of managed care and the needs of the healthcare industry to provide higher quality care at lower costs. Approximately 70 sales and managed care representatives cover approximately 650 hospitals, managed care organizations, and clinics in the U.S., which specialize in pediatric/neonatal care or transplantation for the promotion of Synagis, FluMist and CytoGam, respectively. Approximately 110 biologic sales specialists cover approximately 10,000 pediatric practices in the U.S. for the promotion and detailing of Synagis and FluMist. In addition, approximately 60 oncology/immunology specialists are devoted to sales and marketing of Ethyol to oncologists practicing in cancer treatment centers, large hospitals and private medical practices. In total, the Company now employs approximately 320 people devoted to sales and marketing of its products in the United States.

The Company has also entered into co-promotion agreements for its products. For the promotion of Synagis in the U.S., the Company has a co-promotion agreement with the Ross Products division of Abbott. Through its 500 sales representatives, the Ross Products division details Synagis to approximately 27,000 office-based pediatricians and 6,000 birth hospitals.

8

---

In the U.S., the Company also relies upon specialty distributors and wholesalers to deliver Synagis to its customers, including physicians, hospitals and pharmacies. During 2003, MedImmune launched the Synagis Distribution Network ("SDN"), which significantly reduced the number of distributors involved in the distribution of Synagis to attempt to ensure high-quality and consistent services for patients. There are a relatively small number of specialty distributors who provide such services. There can be no assurances that these distributors will adequately provide their services to either the end users or to the Company, nor can there be any guarantee that these service providers remain solvent. The Company also reduced the number of wholesalers involved with Synagis to properly manage the SDN.

For FluMist, the Company has a co-promotion agreement with Wyeth to market the vaccine in the United States. Through approximately 450 sales representatives, sales managers, and managed care specialists, the Wyeth sales team details FluMist to office-based pediatricians and primary care physicians, while MedImmune's representatives detail the product to pediatric infectious disease/respiratory thought leaders, pharmacies and employers. FluMist is distributed directly to physician's offices, pharmacies, and vaccination clinics by Wyeth.

As discussed in Note 4, "Segment, Significant Customer and Geographic Information," of the Company's Consolidated Financial Statements, the Company has four major customers who individually provided over 10% of its total revenue during the last three years. Note 4 also contains information concerning the geographic areas in which the Company operates. The Company faces risks related to foreign currency exchange rates, as discussed under the caption "Risk Factors Changes in foreign currency exchange rates or interest rates could result in losses."

**Manufacturing and Supply**

MedImmune operates five commercial manufacturing facilities in the U.S. and Europe. In addition, the Company has entered into manufacturing, supply and purchase agreements with other companies to provide certain portions of its production capacity for all of its marketed products and to produce clinical supplies for its development-stage products. Certain materials necessary for the Company's commercial manufacturing of its products are proprietary products of other companies, and in some cases, such proprietary products are specifically cited in the Company's drug application with the FDA such that they must be obtained from that specific, sole source. In addition, certain materials necessary for the Company's commercial manufacturing of its products are only available through one approved single source supplier though it is available from more than one supplier. The Company currently attempts to manage the risk associated with such sole sourced and single sourced materials by active inventory management and, where feasible, alternate source development. MedImmune attempts to remain apprised of the financial condition of its suppliers, their ability to supply the Company's needs and the market conditions for these raw materials. Also, certain materials required in the commercial manufacturing of the Company's products are derived from biological sources. The Company maintains screening procedures with respect to certain biological sources, where appropriate, and is investigating alternatives to them. Raw materials may be subject to contamination and/or recall. A material shortage, contamination, and/or recall could adversely impact or disrupt MedImmune's commercial manufacturing of its products.

**Synagis** The primary manufacturing facility for supply of Synagis in the U.S. is the Company's Frederick Manufacturing Center ("FMC"). The FMC is a biologics facility containing a cell culture production area for the manufacture of recombinant products. Filling and packaging of final Synagis product is completed by two vendors: Sicor, Inc. and Boehringer Ingelheim Pharma KG ("BI").

Supplemental supply of Synagis for the U.S. market is manufactured by BI under a manufacturing and supply agreement. BI also fills and packages Synagis produced at its German facility. As the sole supplier of Synagis for all territories outside the U.S. and supplemental supplier for the U.S. market,

9

BI is responsible for obtaining and maintaining licensure and approval for making the product at its facility from all appropriate regulatory authorities including the FDA. To provide adequate backup for international supply of Synagis, MedImmune will seek to obtain approval from the appropriate international regulatory agencies to sell Synagis made at FMC outside the U.S. The Company plans to continue to rely upon BI for production of additional quantities of Synagis to meet expected worldwide demand for the product and to reduce its reliance for supply of Synagis outside the U.S. to any one manufacturing site.

**Ethylol** All bulk drug substance for Ethylol is produced by contract manufacturers. In 2003, filling and finishing of all product was completed at the Company's manufacturing facility in Nijmegen, the Netherlands. To backup its own filling and finishing capabilities, the Company has an agreement with Ben Venue to fill and finish Ethylol for sale in the U.S.

**CytoGam** CytoGam is produced from human plasma collected from donors who have been screened to have high concentrations of antibodies against cytomegalovirus or respiratory syncytial virus, respectively. The collected human plasma is converted into an intermediate raw material known as Fraction II+III paste. This step was completed at MedImmune's FMC for CytoGam from 2000 until 2002, when the Company made the decision to outsource the process to Precision Pharma Services, Inc. The intermediate paste is processed into bulk product, filled and packaged by the Massachusetts Biologic Laboratories. The Company is exploring opportunities to use its plasma production suite, formerly involved in the manufacture of CytoGam, in a manner that would support the production of its other marketed and developmental-stage recombinant products.

**FluMist** FluMist is produced at several facilities either owned or leased by the Company. The master virus seeds are prepared at the Company's Mountain View, California facility. The bulk monovalents and diluent are produced at facilities leased from Evans Vaccines, a wholly owned subsidiary of Chiron Corporation in Speke, the United Kingdom. Blending of FluMist into its trivalent formulation and filling of the final vaccine into the AccuSpray applicators, the non-invasive nasal spray delivery system developed and supplied by Becton Dickinson, takes place at the Company's Philadelphia, Pennsylvania facility. The Company has begun the initial stages of commercial manufacturing of FluMist for the 2004-2005 influenza season.

#### ***Patents, Licenses and Proprietary Rights***

The products and product candidates currently being developed or considered for development by the Company are in the area of biotechnology, an area in which there is extensive patent filings. The Company relies on patent protection against use of its proprietary products and technologies by competitors. The patent position of biotechnology firms generally is highly uncertain and involves complex legal and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology patents. Accordingly, there can be no assurance that patent applications owned or licensed by the Company will result in patents being issued or that, if issued, such patents will afford meaningful protection against competitors with similar technology. The Company currently owns or in-licenses over 100 patents worldwide related to its products or product candidates. The Company also owns or in-licenses at least 100 additional applications for patents currently pending in the U.S. A list of the U.S. patents the Company owns or in-licenses is filed as an exhibit hereto as Exhibit 99.1 and is incorporated by reference into this document.

The Company believes that there are other patents issued to third parties and/or patent applications filed by third parties that could relate to each of the Company's products and product candidates and could adversely affect the Company's freedom to make, have made, use, have used, sell, or have sold such products or use certain processes for their manufacture. Some of these third parties have contacted the Company claiming patent infringement by the Company. The Company is unable to predict whether it will ultimately be necessary to seek licenses from such third parties or, if such

licenses were necessary, whether such licenses would be available on terms acceptable to the Company. The necessity for such licenses could have a material adverse effect on the Company's business.

There has been substantial litigation regarding patent and other intellectual property rights in the biotechnology industry. Litigation may be necessary to enforce certain intellectual property rights of the Company, or to defend against asserted intellectual property rights of third parties. Any such litigation could result in substantial cost to and diversion of effort by the Company. As described in Note 17 to the Consolidated Financial Statements, the Company has chosen to file litigation to challenge certain intellectual property rights of third parties.

**Government Regulation**

The production and marketing of the Company's products and research and development activities are subject to regulation for safety and efficacy by numerous governmental authorities in the U.S. and other countries. In the U.S., vaccines, biologics, drugs and certain diagnostic products are subject to FDA licensure. The federal Food, Drug and Cosmetics Act, the Public Health Service Act and other federal statutes and regulations govern or influence the testing, manufacture, safety, labeling, storage, record keeping, licensure, advertising and promotion of such products. No assurances can be given that any products under development will be licensed for marketing by the FDA or, if approved, that the product would be successfully commercialized or maintained in the marketplace. Noncompliance with applicable requirements could result in fines, recall or seizure of products, total or partial suspension of production, refusal of the government to approve product license applications, restrictions on the Company's ability to enter into supply contracts and criminal prosecution. The FDA also has the authority to revoke product licenses and establishment licenses previously granted.

*Orphan Drug Designation*

The Orphan Drug Act was established to encourage development of drugs for rare diseases and conditions affecting a small patient population (generally fewer than 200,000 people). Orphan drug designation of a product can potentially provide a company with seven years of market exclusivity if the company is the first to receive FDA product marketing approval for the orphan drug in the designated indication. Additionally, this designation provides a company with tax credits of 50 percent for qualified clinical research expenses and the opportunity for clinical research grants. CytoGam and Ethyol currently qualify as orphan drugs for the following indications: (1) CytoGam has market exclusivity for use in lung, liver, pancreas and heart transplants until December 2005; and (2) Ethyol has market exclusivity for its currently licensed radioprotective indication through June 2006. Ethyol, NeuTrexin and sipilizumab have all been designated as orphan drugs for potential use in indications that have not yet been approved by the FDA as follows:

- (1) Ethyol as a chemoprotective agent for use with cyclophosphamide in the treatment of advanced ovarian carcinoma, as a chemoprotective agent for use with cisplatin in the treatment of metastatic melanoma, for the treatment of myelodysplastic syndromes, and for the reduction of the incidence and severity of cisplatin-induced toxicities;
- (2) NeuTrexin for the treatment of metastatic colorectal adenocarcinoma, metastatic carcinoma of the head and neck, pharynx and larynx, pancreatic adenocarcinoma and advanced non-small cell carcinoma of the lung and osteogenic sarcoma; and
- (3) Sipilizumab for the treatment of graft versus host disease and T-cell lymphoma.

If approved for any of the designated orphan indications, each of these products would have market exclusivity for seven years from the date of FDA approval if it is the first product approved by the FDA for treatment of the designated orphan indication. Orphan drug designations for the use of

Ethyol to prevent side effects of cisplatin in ovarian cancer patients, and the use of RespiGam to prevent RSV disease in high-risk infants expired in 2002 and 2003, respectively.

*Environmental and Safety Regulations*

The Company is also subject to regulation by the Occupational Safety and Health Administration ("OSHA") and the Environmental Protection Agency ("EPA") and to regulation under the Toxic Substances Control Act, the Resources Conservation and Recovery Act and other regulatory statutes, and may in the future be subject to other federal, state or local regulations. OSHA and/or the EPA may promulgate regulations concerning biotechnology that may affect the Company's research and development programs. At any time, any agency may adopt regulations that would have a material adverse effect on the Company's operations and the Company is unable to predict when or whether this might happen. The Company voluntarily attempts to comply with guidelines of the National Institutes of Health regarding research involving recombinant DNA molecules. Such guidelines, among other things, restrict or prohibit certain recombinant DNA experiments and establish levels of biological and physical containment that must be met for various types of research.

*Foreign Regulation*

Sales of pharmaceutical and biopharmaceutical products outside the U.S. are subject to foreign regulatory requirements that vary from country to country. Whether or not FDA licensure has been obtained, licensure of a product by comparable regulatory authorities of other countries must be obtained before marketing the product in those countries. The time required to obtain such licensure may be longer or shorter than that required for FDA approval, and no assurance can be given that such approval will be obtained.

### *Competition*

The biotechnology and pharmaceutical industries are characterized by rapidly evolving technology and intense competition. The Company's competitors include pharmaceutical, chemical and biotechnology companies, many of which have financial, technical and marketing resources significantly greater than those of the Company. In addition, many specialized biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with those of the Company. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint venture arrangements.

The Company is aware of certain potentially competitive products targeting areas of medical interest to the Company, including influenza, RSV, psoriasis, HPV infections, influenza infections, and organ graft rejection. In the prevention of CMV disease, CytoGam competes with several products including other antiviral drugs, such as intravenous and oral ganciclovir and standard immune globulin preparations. The Company is aware that a number of physicians have prescribed CytoGam in combination with ganciclovir for the prevention of CMV disease in certain patients.

The Company believes that Synagis and RespiGam are the only products currently available for the prevention of RSV disease. However, the Company is aware of one product in the U.S., ribavirin, which is indicated for the treatment of RSV disease. The existence of this product, or other products or treatments of which the Company is not aware, or products or treatments that may be developed in the future, may adversely affect the marketability of products developed by the Company.

In relation to flu vaccines, in the past, the Company has been aware of three main distributors of inactivated, injectable vaccines. From these three distributors, approximately 80 million doses of these inactivated vaccines have traditionally been sold annually in the U.S. In 2002, Wyeth announced its

intent to no longer produce the inactivated, injectable vaccine after the completion of the 2002-2003 influenza season. The Company is also aware that Merck has licensed a Russian live virus intranasal vaccine, currently available in Russia, and that ID Biomedical Corporation is developing an intranasal, inactivated flu vaccine that is in the early stages of clinical testing. Any of the products listed here, as well as other products of which the Company is not aware, may adversely affect the marketability of FluMist.

Many companies, including well-known pharmaceutical companies, are marketing anticancer drugs and drugs to ameliorate or treat the side effects of cancer therapies, and are seeking to develop new products and technologies for these applications. Many of these drugs, products and technologies are, or in the future may be, competitive with the Company's oncology products. In the U.S., the Company believes that Aventis SA holds the largest share of the chemotherapy market both in terms of approved products and annual sales, and therefore dominates the marketplace. To the Company's knowledge, other companies maintaining a significant active oncology marketing and sales presence include Amgen, Inc., AstraZeneca, Bristol-Myers Squibb Company, Chiron Corporation, Eli Lilly and Company, Genentech, GSK, Hoffmann-La Roche, Inc., Johnson & Johnson, Pfizer, and Schering-Plough Corporation. Many of these companies have substantially greater financial, technical, manufacturing, marketing and other resources than the Company and may be better equipped than the Company to develop, market and manufacture these therapies. No assurance can be given that the oncology drugs developed by the Company will be able to compete successfully against therapies already established in the marketplace or against new therapies that may result from advances in biotechnology or other fields which may render the Company's oncology drugs less competitive or obsolete. In addition, the Company's oncology drugs may become subject to generic competition in the future.

The Company expects its products to compete primarily on the basis of product efficacy, safety, patient convenience, reliability, and patent position. In addition, the first product to reach the market in a therapeutic or preventive area is often at a significant competitive advantage relative to later entrants to the market. The Company's competitive position will also depend on its ability to attract and retain qualified scientific and other personnel, develop effective proprietary products, implement product and marketing plans, obtain patent protection and secure adequate capital resources.

*Officers and Key Employees of the Company*

Name	Age	Position	Officer/Key Employee Since
Wayne T. Hockmeyer, Ph.D.	59	Chairman of the Board; President, MedImmune Ventures, Inc.	1988
David M. Mott	38	Chief Executive Officer, President and Vice Chairman of the Board	1992
James F. Young, Ph.D.	51	President, Research and Development	1989
Armando Anido, R.Ph.	46	Senior Vice President, Commercial Operations	1999
Edward J. Arcuri, Ph.D.	53	Senior Vice President, Manufacturing Operations	2002
Edward M. Connor, M.D.	51	Senior Vice President, Chief Medical Officer	1999
Gail Folena-Wasserman, Ph.D.	49	Senior Vice President, Development	2002
Bernardus N. Machielse, Drs.	43	Senior Vice President, Quality	2003
Lota S. Zoth, C.P.A.	44	Vice President and Controller, Acting Chief Financial Officer	2004

**Wayne T. Hockmeyer, Ph.D.** Dr. Hockmeyer founded MedImmune, Inc. in April 1988 as President and Chief Executive Officer and was elected to serve on the Board of Directors in May 1988. Dr. Hockmeyer became Chairman of the Board of Directors in May 1993. He relinquished his position as Chief Executive Officer in October 2000 and now serves as the Chairman of the Board of Directors and President of MedImmune Ventures, Inc. Dr. Hockmeyer earned his bachelor's degree from Purdue University and his Ph.D. from the University of Florida in 1972. In 2002, Dr. Hockmeyer was awarded a Doctor of Science *honoris causa* from Purdue University. Dr. Hockmeyer is a member of the Maryland Economic Development Commission. He is also a member of the Board of Directors of Advancis Pharmaceutical Corp., Diversa Corporation, GenVec, Inc., InterMune Pharmaceuticals, Inc., Idenix Pharmaceuticals, Inc., Tercica, Inc., and TolerRx Inc. Dr. Hockmeyer does not intend to seek re-election to the Board of Directors of InterMune Pharmaceuticals, Inc. or Diversa Corporation when his current term on those boards expires in May 2004.

**David M. Mott** Mr. Mott was appointed Chief Executive Officer in October 2000 and was also appointed President in February 2004. He joined the Company in April 1992 as Vice President with responsibility for business development, strategic planning and investor relations. In 1994, Mr. Mott assumed additional responsibility for the medical and regulatory groups, and in March 1995 was appointed Executive Vice President and Chief Financial Officer. In November 1995, Mr. Mott was appointed to the position of President and Chief Operating Officer and was elected to the Board of Directors. In October 1998, Mr. Mott was appointed Vice Chairman. Mr. Mott is Chairman of the Board of Directors of Conceptis Technologies, a member of the board of the Biotechnology Industry Organization (BIO), and also serves on the Board of Trustees of St. James School and on the Board of Governors of Beauvoir, the National Cathedral Elementary School. He holds a Bachelor of Arts degree from Dartmouth College.

**James F. Young, Ph.D.** Dr. Young was promoted to the position of President, Research and Development, in December 2000. Dr. Young joined MedImmune in 1989 as Vice President, Research and Development. In 1995, he was promoted to Senior Vice President and in 1999 he was promoted to Executive Vice President, Research and Development. Dr. Young received his doctorate in

microbiology and immunology from Baylor College of Medicine in Houston, Texas, and Bachelor of Science degrees in biology and general science from Villanova University. Dr. Young is a member of the Board of Directors of Iomai Corporation.

**Armando Anido, R.Ph.** Mr. Anido was appointed Senior Vice President, Commercial Operations in February 2004. He joined the Company in 1999 as Senior Vice President, Sales and Marketing. Prior to joining the Company, Mr. Anido was Vice President of CNS Marketing at Glaxo Wellcome, Inc. from 1996 to 1999. Prior to this time, Mr. Anido served in various positions at Lederle Laboratories from 1989 to 1995, culminating in his service as the Vice President of Anti-Infectives Marketing. Mr. Anido is a registered pharmacist, and holds a Bachelor of Science in pharmacy and a Master of Business Administration degree from West Virginia University.

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

**Edward J. Arcuri, Ph.D.** Dr. Arcuri was promoted to the position Senior Vice President, Manufacturing Operations in September 2003. Previously, Dr. Arcuri served as Senior Vice President, Manufacturing, MedImmune Vaccines, since joining MedImmune as a part of the Company's acquisition of Aviron in January 2002. Dr. Arcuri was Senior Vice President, Operations, of Aviron since May 2000. He joined Aviron as Vice President, Manufacturing, in July 1999. Prior to joining Aviron, Dr. Arcuri served as Vice President, Manufacturing Operations and Process Development for North American Vaccine, Inc., or NAVA, from January 1995 to July 1999. Prior to joining NAVA, Dr. Arcuri served as Senior Director, Biological Manufacturing, at Merck & Co., Inc. from 1991 to 1994. Dr. Arcuri holds a B.S. degree in Biology from the State University of New York at Albany and a master's degree and Ph.D. in Biology from Rensselaer Polytechnic Institute.

**Edward M. Connor, M.D.** Dr. Connor was appointed Senior Vice President, Chief Medical Officer in February 2004. He joined the Company in 1994 as the Director of Clinical Studies and was promoted in 1995 to Vice President of Clinical Development and in 1999 to Senior Vice President, Clinical Development. Dr. Connor holds a bachelor's degree in biology from Villanova University and a medical degree from University of Pennsylvania School of Medicine. He is board certified in pediatrics and is a consultant in pediatric infectious diseases.

**Gail Folena-Wasserman, Ph.D.** Dr. Folena-Wasserman was promoted to Senior Vice President, Development in February 2002. She joined the Company in 1991 as Director, Development and was promoted to Vice President, Development in October 1995. Prior to joining the Company, she spent nine years in natural products isolation and biopharmaceutical process development at SmithKline Beecham Pharmaceuticals. Dr. Folena-Wasserman holds a bachelor's degree in biology and chemistry from Montclair State College in New Jersey, and has a master's degree in biochemistry and a doctorate in chemistry from Pennsylvania State University.

**Bernardus N. Machielse, Drs.** Drs. Machielse was appointed Senior Vice President, Quality, in September 2003. Drs. Machielse joined MedImmune in May 1999 as Vice President, Quality. Prior to joining MedImmune, Drs. Machielse was Vice President of Quality Control and Quality Assurance for Xoma Corporation of Berkeley, California. He also spent several years in various manufacturing and quality positions at Centocor BV of the Netherlands. Drs. Machielse holds a Bachelor of Science degree in Medical Biology and a Master of Science degree in Biochemistry from the University of Utrecht, The Netherlands.

**Lota S. Zoth, C.P.A.** Ms. Zoth became Acting Chief Financial Officer of MedImmune in January 2004. She joined the Company in August 2002 as Vice President and Controller. Prior to joining MedImmune, Ms. Zoth was Senior Vice President and Corporate Controller for PSINet, Inc, who filed a petition for bankruptcy on May 31, 2001. Between 1998 and 2000, Ms. Zoth was Vice President, Corporate Controller and Chief Accounting Officer of Sodexho Marriott Services, Inc. Prior to Sodexho Marriott, Ms. Zoth was Vice President, financial analysis, for Marriott International, Inc.'s food and management services division. Ms. Zoth is a CPA, and holds a B.B.A. in accounting from Texas Tech University.

15

---

### *Employees*

The Company considers relations with its employees to be good. As of December 31, 2003, the Company had approximately 1,650 full-time permanent employees.

Approximately 100 of the Company's employees in The United Kingdom are members of a labor union, with which the Company renegotiates employment terms periodically. There can be no guarantee that the annual negotiations will lead to an outcome that is favorable to the Company. If negotiations were to break down between the Company and the union, there can be no guarantee that the Company would be able to manufacture an adequate supply of FluMist.

### *Risk Factors*

In addition to the other information included in this report, you should consider the following risk factors. This report contains forward-looking statements covered by the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties that may affect the Company's business and prospects. MedImmune's results may differ significantly from the results discussed in the forward-looking statements as a result of certain factors that are listed below or discussed elsewhere in this report and the Company's other filings with the Securities and Exchange Commission.

### **The Company's revenues are largely dependent on sales of Synagis.**

Sales of Synagis accounted for approximately 86% of the Company's total product sales in 2003 and the Company's revenues will continue to be largely dependent on sales of Synagis for the foreseeable future. Any perceived or actual event or series of events that have an effect on sales of Synagis will have a detrimental impact on the Company. Events which would affect sales of Synagis include, but are not limited to, any

product liability claims (whether supported or not), any manufacturing or supply delays, any sudden loss of inventory, any inability to satisfy product demand, any unsuccessful sales or marketing strategies and any change in the reimbursement rate for Synagis by private or public insurance carriers or programs. In addition, Synagis is a biological product regulated and approved for marketing in the U.S. by the FDA and any adverse change in the marketing approval or label for Synagis required by the FDA will have a detrimental impact on the Company. The Company has also created an exclusive network for distribution of Synagis, which will have the effect of preventing certain entities from obtaining Synagis and may have the effect of changing the reimbursement rate for Synagis by private or public insurance carriers or programs, any of which could result in reduced sales.

**The seasonal nature of a significant portion of Company's business causes significant fluctuations in quarterly operating results.**

Sales of three of the Company's products, Synagis, FluMist, and RespiGam, are seasonal in nature. Synagis and RespiGam sales occur primarily in the first and fourth quarters of the calendar year and FluMist sales occur primarily in the fourth quarter of the calendar year. This high concentration of product sales in a portion of the year causes quarter-to-quarter operating results to vary widely and would exaggerate the adverse consequences on the Company's revenues of any manufacturing or supply delays, any sudden loss of inventory, any inability to satisfy product demand, the inability to estimate the impact of returns and rebates, or of any unsuccessful sales or marketing strategies during the applicable sales season. Furthermore, the Company's current product base would limit its ability to offset in the second and third quarters any lower-than-expected sales of Synagis during the first and fourth quarters.

16

---

**The Company may not be able to successfully commercialize FluMist.**

There can be no assurance that FluMist will achieve commercial success. There are a number of factors which make the commercialization of FluMist difficult. These factors include, but are not limited to, significant competition in the marketplace by other influenza virus vaccines, the higher cost of manufacturing FluMist relative to competing vaccines, perceived or actual risks related to the use of a live virus vaccine, lack of acceptance by the targeted patient population of the need for vaccination against influenza, lack of reimbursement coverage by private or public insurance carriers or programs, lack of product accessibility by potential consumers, an inability to develop alternative channels for sales, such as pharmacies, due to state or federal regulations or for other reasons and difficult storage requirements for the transport and storage of the product. Furthermore, commercialization is dependent upon successful manufacturing of the product, which may be adversely affected if the Company is unable to perform the complex annual update of the FluMist formulation for new influenza strains, if there are problems or difficulties in the complex manufacturing process or if there is a sudden loss of inventory. There can also be no assurance that the Company could successfully manufacture a quadravalent vaccine, should such a vaccine ever be required. The Company's FluMist product sales revenues are dependent to a large extent on the price at which doses are sold (which is set by Wyeth) and the number of returned doses (which is governed by Wyeth's return goods policy). Since these values are not within the Company's control, there can be no assurance that the Company's cost of goods will not exceed its revenues for this product. If the Company is unable to successfully commercialize FluMist, the anticipated benefits of its acquisition of Aviron may not be realized, and the Company's results of operations would be negatively impacted by impairment charges for the write-down of manufacturing and intangible assets related to FluMist.

**The Company may not be able to bring its product candidates to market.**

Research and development activities are costly and may not be successful, and there can be no assurance that any of the Company's product candidates will be approved for marketing by the FDA or the equivalent regulatory agency of any other country. A significant portion of the Company's annual operating budget is spent on research, development and clinical activities. Currently, numerous products are being developed that may never reach clinical trials, achieve success in the clinic, be submitted to the appropriate regulatory authorities for approval, or be approved for marketing or manufacturing by the appropriate regulatory authorities. There can also be no assurance that the Company will be able to generate additional product candidates for its pipeline, either through internal research and development, or through the in-licensing of products or technology. Even if a product candidate is approved for marketing by the applicable regulatory agency, there can be no assurance that the Company will be able to successfully manufacture the product on a commercial scale or effectively commercialize the product.

**A significant portion of the Company's business is dependent on third parties.**

The Company licenses a significant portion of the technology necessary for its business from third parties and relies on third parties for a significant portion of the clinical development, supply of components, manufacturing, distribution, and promotion of the Company's products. The actions of these third parties are outside of the Company's control and the failure of these third parties to act in accordance with their obligations to the Company would have a material adverse effect on the Company's business. Even if the Company is legally entitled to damages for a failure of a third party to fulfill its obligations to the Company, there can be no assurance that such damages will adequately compensate the Company for indirect or consequential losses such as the damage to a product brand or the Company's reputation. If a third party does not fulfill its obligations to the Company, the Company may have to incur substantial additional costs, which could have a material adverse effect on the Company's business.

---

**Defending product liability claims could be costly and divert focus from the Company's business operations and product recalls may be necessary.**

The Company's products contain biologically active agents that can have the effect of altering the physiology of the person using the product. Accordingly, as a developer, tester, manufacturer, marketer and seller of biological products, the Company may be subject to product liability claims that may be costly to defend regardless of whether the claims have merit. If a claim were to be successful, there is no guarantee that the amount of the claim would not exceed the limit of the Company's insurance coverage. Further, a successful claim could reduce revenues related to the product, result in the FDA taking regulatory action (including suspension of product sales for an indefinite period) or result in significant negative publicity for the Company or damage to the product brand. Any of these occurrences could have a material adverse effect on the Company's business and could result in a clinical trial interruption or cancellation. Additionally, product recalls may be necessary either in connection with product liability claims or for other reasons. Any such recall would adversely affect sales of that product.

**The Company may not be able to meet the market demand for its products.**

The Company generally does not have or contract for redundant supply, production, packaging or other resources to manufacture its products. As a result, the Company is at risk for business interruption if there is any disruption in the manufacturing chain. Difficulties or delays in the Company's or the Company's contractors' manufacturing of existing or new products could increase the Company's costs, cause the Company to lose revenue or market share and damage the Company's reputation. In addition, because the Company's various manufacturing processes and those of its contractors are highly complex and are subject to a lengthy FDA approval process, alternative qualified production capacity may not be available on a timely basis or at all.

**The Company may lose product due to difficulties in the manufacturing process.**

The Company's manufacturing operations expose it to a variety of significant risks, including: product defects; contamination of product or product loss; environmental problems resulting from our production process; sudden loss of inventory and the inability to manufacture products at a cost that is competitive with third party manufacturing operations. Furthermore, MedImmune has not produced FluMist for commercial use for a sustained period and may encounter additional unforeseeable risks as the Company develops additional commercial manufacturing experience with this product. In addition, the Company's facilities in the United Kingdom are unionized and may be subject to manufacturing interruptions due to labor action.

**Contamination of our raw materials could adversely affect the Company.**

As with other biotechnology companies, the manufacture of our products requires raw materials obtained from a variety of sources including but not limited to animal products or by-products. If these raw materials contain contaminants that are not removed by our approved purification processes, it could result in a material adverse effect on our product sales, financial condition and results of operations and might negatively impact our ability to manufacture those products for an indefinite period of time, regardless of whether such contamination has any proven effect on the safety or efficacy of the product.

**Reimbursement by government and third-party payers is critical for the success of the Company's products.**

The cost to individual consumers for purchase of the Company's products can be significant. Accordingly, sales of Company products are dependent to a large extent on the insurance

---

reimbursement available for the Company's products. Actions by government and third-party payers to contain or reduce the costs of health care by limiting reimbursement, increasing procedural hurdles to obtain reimbursement or by other means may have a material adverse effect on sales of the Company products. In addition, there have been numerous proposals in the U.S., both at the state and federal level, as well as in other countries that would, if adopted, affect the reimbursement of the Company's products and have a material adverse effect on the Company's business.



**The Company relies upon a limited number of pharmaceutical wholesalers and distributors that could impact the ability to sell the Company's products.**

The Company relies largely upon specialty pharmaceutical distributors and wholesalers to deliver its currently marketed products to the end users, including physicians, hospitals, and pharmacies. There can be no assurance that these distributors and wholesalers will adequately fulfill the market demand for the Company's products, nor can there be any guarantee that these service providers will remain solvent. Given the high concentration of sales to certain pharmaceutical distributors and wholesalers, the Company could experience a significant loss if one of its top customers were to declare bankruptcy or otherwise become unable to pay its obligations to MedImmune.

**Obtaining and maintaining regulatory approvals to develop, manufacture and market the Company's products is costly and time consuming.**

The development, manufacturing and marketing of all of the Company's products are subject to regulatory approval by the FDA in the U.S., as well as similar authorities in other countries. The approval process for each product is lengthy and subject to numerous delays, which are generally not in the Company's control. There can be no assurance that any product candidate will be approved for marketing and, if approved, such approval may be limited in scope in such a manner that would harm the product's potential for market success. Even after a product is approved for marketing, it is still subject to continuing regulation. For example, if adverse event information about a product becomes available, the Company may be required by applicable authorities to recall the product or notify health care providers of additional risks associated with use of the product. In addition, even if the Company has complied with all applicable laws and regulations, the applicable regulatory authorities have the authority to and may revoke or limit approvals or licenses without consulting or obtaining the consent of the Company. If the Company fails to comply with applicable requirements, it may be subject to: fines; seizure of products; total or partial suspension of production; refusal by the applicable authority to approve product license applications; restrictions on the Company's ability to enter into supply contracts; and criminal prosecution. If the Company is unable to obtain approvals on a timely basis or at all, if the scope of approval is more limited than expected by the Company or if the Company is unable to maintain approvals, its ability to successfully market products and to generate revenues will be impaired.

**Patent protection for the Company's products may be inadequate or costly to enforce.**

The Company may not be able to obtain effective patent protection for its products in development. There are extensive patent filings in the biotechnology industry and the patent position of biotechnology companies generally is highly uncertain and involves complex legal and factual questions. There can be no assurance that the Company's patent applications will result in patents being issued or that, if issued, such patents will afford protection against competitors with similar technology. Litigation may be necessary to enforce MedImmune's intellectual property rights. Any such litigation will involve substantial cost and significant diversion of the Company's resources and there can be no assurance that any of the Company's litigation matters will result in an outcome that is beneficial to the Company.

19

---

**If the Company fails to obtain and maintain any required intellectual property licenses from third parties, its product development and marketing efforts will be limited.**

Patents have been and will be issued to third parties, and patent applications have been filed by third parties, that claim one or more inventions used in the development, manufacture or use of the Company's products or product candidates. These patents (including any patents issuing from pending patent applications), if valid and enforceable, would preclude the Company's ability to manufacture, use or sell these products unless the Company obtains a license from the applicable third party. These third parties are not generally required to provide the Company with a license and, as such, obtaining any such licenses may not be possible or could be costly and impose significant royalty burdens on the Company. There can be no assurance that a license will be available on terms acceptable to the Company or at all, which could have a material adverse effect on the Company's business. In addition, there can be no assurance that the Company will be able to obtain an exclusive license to any such patent, and as a result, the third parties or their sublicensees may be able to produce products that compete with those of the Company. Litigation may be necessary to challenge the intellectual property rights of third parties and would involve significant cost and significant diversion of management's time and resources. There can be no assurance that any such litigation will result in an outcome that is beneficial to the Company.

**Technological developments by competitors may render the Company's products obsolete.**

If competitors were to develop superior products or technologies, the Company's products or technologies could be rendered noncompetitive or obsolete. Developments in the biotechnology and pharmaceutical industries are expected to continue at a rapid pace. Success depends upon achieving and maintaining a competitive position in the development of products and technologies. Competition from other

biotechnology and pharmaceutical companies can be intense. Many competitors have substantially greater research and development capabilities, marketing, financial and managerial resources and experience in the industry. If a competitor develops a better product or technology, the Company's products or technologies could be rendered obsolete, resulting in decreased product sales and a material adverse effect to the Company's business. For example, the master virus donor strain used to create FluMist is not protected by patents and is, instead, protected by trade secrets associated with the technology of creating cold-adapted, temperature sensitive live influenza virus vaccines. There can be no assurance that a competitor will not create a competing influenza virus vaccine based upon similar technologies. Even if a competitor creates a product that is not technologically superior, the Company's products may not be able to compete with such products, decreasing the Company's sales.

**The Company is subject to numerous complex laws and regulations and compliance with these laws and regulations is costly and time consuming.**

U.S. federal government entities, most significantly the FDA, the U.S. Securities and Exchange Commission, the Internal Revenue Service, The Occupational Safety & Health Administration, the Centers for Medicare and Medicaid Services and the U.S. Department of Veteran's Affairs, as well as regulatory authorities in each state and other countries have each been empowered to administer certain laws and regulations applicable to the Company. Many of the laws and regulations administered by these agencies are complex and compliance requires substantial time, effort and consultation with outside advisors by the Company. Because of this complexity, there can be no assurance that the Company's efforts will be sufficient to ensure compliance or to ensure that it is in technical compliance with all such laws and regulations at any given time. In addition, the Company is subject to audit, investigation and litigation by each of these entities to ensure compliance, each of which can also be time consuming, costly, divert the attention of senior management and have a significant impact on the Company's business, even if the Company is found to have been in compliance or the extent of the Company's non-compliance is deemed immaterial. If the Company is found to not be in compliance

20

---

with any of these laws and regulations, the Company and, in some cases its officers, may be subject to fines, penalties, criminal sanctions and other liability, any of which could have a material adverse effect on the Company's business.

**The Company may not be able to hire or retain highly qualified personnel or maintain key relationships.**

The success of the Company's business depends, in large part, on its continued ability to attract and retain highly qualified scientific, manufacturing and sales and marketing personnel, as well as senior management such as Mr. David M. Mott, the Company's Chief Executive Officer, President and Vice Chairman and Dr. James F. Young, the Company's President, Research and Development. In addition, the Company relies on its ability to develop and maintain important relationships with leading research institutions and key distributors. Competition for these types of personnel and relationships is intense among pharmaceutical, biopharmaceutical and biotechnology companies, and the Company's inability to attract or retain such employees and relationships could have a material effect on its business. The Company does not maintain or intend to purchase "key man" life insurance on any of its personnel and, accordingly, the Company's business may be subject to disruption upon the sudden or unexpected loss of a key employee.

**If the Company fails to manage its growth properly, the business will suffer.**

The Company has expanded significantly in recent years due to both acquisition and internal growth. To accommodate its rapid growth and compete effectively, the Company will need to continue to improve its management, operational and financial information systems and controls, generate more revenue to cover a higher level of operating expenses, continue to attract and retain new employees, accurately anticipate demand for products manufactured and maintain adequate manufacturing capacity. This rapid growth and increased scope of operations present risks not previously encountered and could result in substantial unanticipated costs and time delays in product manufacture and development, which could materially and adversely affect the business.

**Fluctuations in MedImmune's common stock price over time could cause stockholders to lose investment value.**

The market price of MedImmune's common stock has fluctuated significantly over time, and it is likely that the price will fluctuate in the future. During 2003, the daily closing price of MedImmune common stock on the Nasdaq stock market ranged from a high of \$40.30 to a low of \$23.30. Investors and analysts have been, and will continue to be, interested in the Company's reported earnings, as well as how the Company performs compared to their expectations. Announcements by the Company or others regarding operating results, existing and future collaborations, results of clinical trials, scientific discoveries, commercial products, patents or proprietary rights or regulatory actions may have a significant effect on the market price of the Company's common stock. In addition, the stock market has experienced extreme price and volume fluctuations that have particularly affected the market price for many biotechnology companies and that have often been unrelated to the

operating performance of these companies. These broad market fluctuations may adversely affect the market price of MedImmune common stock.

**Changes in foreign currency exchange rates or interest rates could result in losses.**

The Company has entered into a supplemental manufacturing contract denominated in Euros. Fluctuations in the Euro U.S. Dollar exchange rate would lead to changes in the U.S. Dollar cost of manufacturing. To reduce the risk of unpredictable changes in these costs, the Company may, from time to time, enter into forward foreign exchange contracts. However, due to the variability of timing and amount of payments under this contract, the forward foreign exchange contracts may not mitigate

21

---

the potential adverse impact on the Company's financial results. In addition, expenditures relating to the Company's manufacturing operations in the United Kingdom and the Netherlands are paid in local currency. MedImmune has not hedged its expenditures relating to these manufacturing operations, and therefore foreign currency exchange rate fluctuations may result in increases or decreases in the amount of expenditures recorded. Additionally, certain of the Company's distribution agreements outside the U.S. provide for it to be paid based upon sales in local currency. As a result, changes in foreign currency exchange rates could adversely affect the amount the Company expects to collect under these agreements.

***Investor Information***

MedImmune files annual, quarterly and current reports, proxy statements and other information with the SEC. You can inspect, read and copy these reports, proxy statements and other information at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549.

You can also obtain copies of these materials at prescribed rates by writing to the Public Reference Section of the SEC at 450 Fifth Street, N.W., Washington, D.C. 20549. You can obtain information on the operation of the public reference facilities by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site (<http://www.sec.gov>) that makes available reports, proxy statements and other information regarding issuers that file electronically with it.

MedImmune makes available free of charge on or through its internet website its annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as reasonable practicable after such material is electronically filed with or furnished to the SEC. MedImmune's internet address is <http://www.medimmune.com>. The information on MedImmune's website is not incorporated by reference into this report.

**ITEM 2. PROPERTIES**

The Company's principal executive and administrative offices and research and development facilities are located in Gaithersburg, Maryland. The facilities occupy approximately 119,000 square feet (including the facilities on West Watkins Mill Road and at the Wind River facility) and are leased until 2006. As of February 29, 2004, the Company has substantially completed construction of the first phase of a new headquarters facility, a complex totaling 220,000 square feet consisting of a research and development facility and administrative offices. The Company owns the land and facility, and expects to take occupancy in March 2004. At that time, the Company may sublease some portion of its current facilities. The Company has also purchased 11.9 additional acres of land at the headquarters site for its anticipated future expansion of the headquarters facility.

The Company also owns 56,000 square feet of administrative and warehouse space and a 91,000 square foot biologics facility in Frederick, Maryland. The biologics facility includes a cell culture production area used for manufacture of Synagis and development-stage projects. Until December 2002, this facility was also used for the manufacture of immune globulins and by-products from human plasma. In addition, in Nijmegen, the Netherlands, the Company owns an 18,000 square foot manufacturing facility on 36,000 square feet of land and leases approximately 9,000 square feet of warehouse space through December 2005.

MedImmune Vaccines operates a number of facilities, including: 102,000 square feet of office and laboratory space in Mountain View, California, which is leased through October 2005 with two options to extend for successive five-year periods; approximately 55,000 square feet of space in Philadelphia, Pennsylvania, pursuant to a lease agreement through December 2004, with options to extend for up to two terms of three years each; approximately 72,000 square feet of office, laboratory and warehouse space in Bensalem, Pennsylvania, pursuant to a lease agreement through June 2008; approximately 72,000 square feet of office, laboratory and manufacturing space in Santa Clara, California,

pursuant to

22

a lease agreement through January 2019, with an option to renew for seven years and approximately 22,500 square feet of office space, expiring in October 2004; approximately 8,900 square feet of a manufacturing facility in Speke, the United Kingdom, pursuant to a sublease expiring in June 2006. In Speke, MedImmune Vaccines also leases approximately eight acres of land near its existing site, which includes a 60,700 square foot structure, through 2025. In addition, MedImmune Vaccines leases approximately 5,100 square feet of office space in Speke under short-term leases.

The Company believes that its current facilities and anticipated additions are adequate to meet its research and development, commercial production, and administrative needs for the near term.

### ITEM 3. LEGAL PROCEEDINGS

Information with respect to legal proceedings is included in Note 17 of Item 8 Consolidated Financial Statements and Supplementary Data and is incorporated herein by reference.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not Applicable

23

## PART II

### ITEM 5. MARKET FOR MEDIMMUNE, INC.'S COMMON STOCK AND RELATED SHAREHOLDER MATTERS

The Company's common stock trades on The Nasdaq National Market under the symbol "MEDI." At February 29, 2004, the Company had 1,975 common stockholders of record. This figure does not represent the actual number of beneficial owners of common stock because shares are generally held in "street name" by securities dealers and others for the benefit of individual owners who may vote the shares.

The following table shows the range of high and low prices and year-end closing prices for the common stock for the two most recent fiscal years.

	2003		2002	
	High	Low	High	Low
First Quarter	\$ 34.60	\$ 26.80	\$ 48.35	\$ 37.30
Second Quarter	42.09	31.52	41.05	24.80
Third Quarter	40.88	31.69	30.43	20.37
Fourth Quarter	35.00	22.79	29.24	20.45
Year End Close	\$ 25.38		\$ 27.17	

The Company has never declared or paid any cash dividends on its common stock and does not anticipate paying any cash dividends in the foreseeable future. The Company currently intends to retain any earnings to fund future growth, product development and operations.

**Recent Sales of Unregistered Securities**

On July 15, 2003, the Company issued and sold an aggregate principal amount of \$500,000,000 of 1% convertible senior notes due 2023 in a transaction not involving a public offering in reliance on an exemption from registration under Section 4(2) of the Securities Act of 1933 (the "Securities Act"). The initial purchasers of the notes in that offering were UBS Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated. These initial purchasers purchased the convertible notes at an aggregate purchase price equal to 98% of the aggregate principal amount of the convertible notes. We have been advised by the initial purchasers that they resold the notes only to "qualified institutional buyers" in reliance on Rule 144A under the Securities Act. Under certain specified circumstances, the notes are convertible into 14.6671 shares of our common stock, par value \$0.01 per share, per \$1,000 principal amount of notes, subject to adjustment. This results in an initial conversion price of approximately \$68.18 per share. The notes also have a contingent interest feature requiring contingent interest to be paid to holders of the notes in certain specified circumstances.

24

**ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA**

	2003	2002(1,3)	2001(3)	2000(3)	1999(2,3)
(in thousands, except per share data)					
<b>RESULTS FOR THE YEAR</b>					
Total revenues	\$ 1,054,334	\$ 852,684	\$ 620,664	\$ 541,955	\$ 384,361
Gross profit	702,798	589,065	442,807	369,943	267,608
Earnings (loss) before cumulative effect of a change in accounting principle	183,204	(1,098,015)	148,960	144,977	93,371
Net earnings (loss)	183,204	(1,098,015)	148,960	111,156	93,371
Basic earnings (loss) per share					
Earnings (loss) before cumulative effect of a change in accounting principle	0.73	(4.40)	0.70	0.69	0.49
Net earnings (loss)	0.73	(4.40)	0.70	0.53	0.49
Diluted earnings (loss) per share					
Earnings (loss) before cumulative effect of a change in accounting principle	0.72	(4.40)	0.68	0.66	0.44
Net earnings (loss)	0.72	(4.40)	0.68	0.50	0.44

**YEAR END POSITION**

Cash and marketable securities	\$ 1,900,149	\$ 1,423,056	\$ 777,690	\$ 526,254	\$ 270,394
Total assets	2,794,670	2,188,289	1,236,855	1,016,597	657,210
Long-term debt	682,076	218,356	9,544	10,302	11,856
Shareholders' equity	1,699,218	1,677,234	1,044,273	843,582	537,079

**PRO FORMA RESULTS**

The following data represents the Company's pro forma financial results assuming retroactive adoption of the change in accounting principle (SAB 101)

Total revenues	\$ 541,955	\$ 386,208
Net earnings	144,977	94,505
Earnings per share		

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

	<u>2003</u>	<u>2002(1,3)</u>	<u>2001(3)</u>	<u>2000(3)</u>	<u>1999(2,3)</u>
Basic				0.69	0.50
Diluted				0.66	0.45

- (1) Includes a charge for acquired in-process research and development, in connection with the Company's acquisition of MedImmune Vaccines, Inc. (formerly Aviron) on January 10, 2002, and the results of operations of MedImmune Vaccines from the acquisition date.
- (2) Includes deferred income tax benefit of \$40,973.
- (3) Certain prior year amounts have been reclassified to conform to the current year presentation.

25

**QUARTERLY FINANCIAL DATA (UNAUDITED)**

	<u>Dec. 31</u>	<u>Sept. 30(3)</u>	<u>June 30(3)</u>	<u>March 31(3)</u>
	(thousands, except per share amounts)			
<i>2003 Quarter Ended</i>				
Net product sales	\$ 398,566	\$ 82,283	\$ 80,596	\$ 431,109
Gross profit	266,339	51,757	56,933	327,769
Net earnings (loss)	76,599	(16,370)	13,454	109,521
Net earnings (loss) per share:				
Basic	\$ 0.31	\$ (0.07)	\$ 0.05	\$ 0.44
Diluted	\$ 0.30	\$ (0.07)	\$ 0.05	\$ 0.43
	<u>Dec. 31(3)</u>	<u>Sept. 30(3)</u>	<u>June 30(3)</u>	<u>March 31(3)</u>
<i>2002 Quarter Ended(1)</i>				
Net product sales	\$ 351,003	\$ 60,842	\$ 57,866	\$ 321,195
Gross profit	267,632	38,273	42,081	241,079
Net earnings (loss)	84,591	(36,292)	(29,456)	(1,116,858)(2)
Net earnings (loss) per share:				
Basic	\$ 0.34	\$ (0.14)	\$ (0.12)	\$ (4.54)(2)
Diluted	\$ 0.33	\$ (0.14)	\$ (0.12)	\$ (4.54)(2)

- (1) Includes the results of operations of MedImmune Vaccines beginning January 10, 2002.
- (2) Includes a \$1,179.3 million charge for acquired in-process research and development in connection with the Company's acquisition of MedImmune Vaccines.
- (3) Certain amounts have been reclassified to conform to the current presentation.

26

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*This Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements regarding future events and our future results that are based on current expectations, estimates, forecasts, and the beliefs and assumptions of our management. Readers are cautioned that these forward-looking statements are only predictions and are subject to risks, uncertainties, and assumptions that are difficult to predict. Readers are referred to the "Forward-Looking Statements" and "Risk Factors" sections in Part I, Item 1 of this document.*

### INTRODUCTION

Since 1988, MedImmune has been focused on using biotechnology to produce innovative products to prevent or treat infectious disease, autoimmune disease and cancer. In January 2002, we acquired Aviron a California-based vaccines company (the "Acquisition") subsequently renamed MedImmune Vaccines, Inc. The operating results of MedImmune Vaccines, Inc. have been included in our consolidated operating results beginning January 10, 2002.

MedImmune currently actively markets four products, Synagis, Etyhol, CytoGam and FluMist and has a diverse pipeline of development-stage products. We are focused on developing important new products, particularly vaccines and antibodies that address significant medical needs in the areas of infectious diseases, immunology and oncology.

Aviron's leading product candidate at the time of the Acquisition was FluMist, the first U.S. vaccine delivered as a nasal mist. On June 17, 2003, the biologics license application for the commercial sale of FluMist was approved by the FDA. FluMist is indicated for active immunization for the prevention of disease caused by influenza A and B viruses in healthy people, 5 to 49 years of age. MedImmune manufactures FluMist and co-promotes FluMist with Wyeth.

### OVERVIEW

The Company's financial condition strengthened from 2002 to 2003, with cash and marketable securities increasing from \$1.4 billion to \$1.9 billion. We improved our capital structure by issuing \$500 million of 1% Convertible Senior Notes (the "1% Notes") on favorable terms. We used the proceeds from the 1% Notes to reinvest in our company through the repurchase of \$229.8 million in common shares which are held in treasury and capital expansion of our research and development, manufacturing and administrative facilities. From an operating results perspective, our diluted earnings per share in 2003 were \$0.72 compared to a net loss per share in 2002 of \$4.40. Excluding the impact of the Acquisition, diluted earnings per share grew 81% from \$0.42 in 2002 to \$0.76 in 2003. We also surpassed the one billion dollar mark for revenues, which totaled \$1.05 billion in 2003. While we were disappointed with the launch year results of the recently-approved FluMist product, the Company continued to show strong top-line and bottom-line year-over-year growth, and improved financial condition as of December 31, 2003.

As we look to the future, we intend to continue commercializing our core products and developing our pipeline, with the long-term goal of strong revenue and earnings growth. The disappointing launch of FluMist in 2003 caused us to reassess our expectations of near-term growth for FluMist. We have completed a reevaluation of the FluMist program, and we intend to continue to develop the product. We are refocusing on this development over the next two or three years, and we do not expect FluMist to be profitable before 2007. We have not yet made final decisions regarding price, forecast or structure of the Wyeth relationship for the 2004/2005 influenza season and beyond.

Other product development objectives include a target of three new INDs in each of 2004, 2005 and 2006. We anticipate that we will have four products in Phase 3 in 2005. Further, we anticipate having at least two new product introductions over the next five years.

We also have the following expectations for 2004:

*Product sales* We believe that the growth rate of our product sales, while still at double-digit levels, will decelerate in 2004. Due to the significant contribution of Synagis, we believe our revenues and operating results will reflect for the foreseeable future the seasonality of that product's use to prevent RSV disease, which occurs primarily during the winter months. We do not expect FluMist sales in the 2004/2005 influenza season to exceed sales from the 2003/2004 influenza season.

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

*Other revenues* We anticipate the level of other revenues to decrease in 2004 largely due to decreases in milestone payments associated with the approval and commercialization of FluMist. The level of contract revenues in future periods will depend primarily upon the extent to which we enter into other collaborative contractual arrangements, if any, and the extent to which we achieve certain milestones provided for in existing agreements. Future revenues from the sale of excess production capacity will vary depending upon the extent to which we enter into these types of arrangements, and are not expected to be significant for 2004 or thereafter.

*Gross margin* We expect that gross margins may vary significantly from quarter to quarter, based on the product mix. We expect that our annual gross margin percentage for 2004 will be lower than 2003, largely the result of the low volume of FluMist revenues to cover the manufacturing costs of the product.

*Research and development expense* We expect research and development expenses to increase significantly in 2004 compared to 2003. This is largely due to the initiation of four Phase 2 studies for Vitaxin, post-marketing commitments and additional trials associated with FluMist, and the continued progress of Numax and our other pipeline candidates.

In the event that MedImmune were to allow Wyeth to exit from the FluMist relationship in 2004, we would write off approximately \$75 million of unamortized intangible assets and would likely incur additional operating expenses.

Over the next five years, we believe our financial position will strengthen, as we anticipate that our cash and marketable securities, net of debt repayments, repurchases of common stock, capital expansion funding and research and development expenditures, will grow.

### CRITICAL ACCOUNTING ESTIMATES

The preparation of consolidated financial statements requires us to make estimates and judgments with respect to the selection and application of accounting policies that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosures of contingent assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting estimates have the greatest impact on the preparation of our consolidated financial statements.

**Revenue Recognition** We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectibility is reasonably assured. During 2003, we shipped 4.1 million doses of FluMist to Wyeth and received payments totaling \$51.9 million. Wyeth is contractually responsible for distributing the product to third parties. At the end of the influenza season, Wyeth's actual net sales for the season are used to calculate the final transfer price per dose and the amount of product royalties due to MedImmune. Actual net sales consists of any amounts actually received by Wyeth for the sale of FluMist less agreed-upon amounts paid or credited by Wyeth related to the sale of the product such as for returns, promotional

28

---

discounts, rebates, taxes and freight. Prior to the calculation of actual net sales, our ability to recognize revenue is dependent upon our ability to estimate the sales volume for the season and the expected impact of the reduction to sales. As of December 31, 2003, we concluded that the variables associated with the product transfer price were not determinable, largely due to low sales volume and the lack of returns history and comparable rebate redemption rates for rebates for this new product. As a result, we have not recognized the revenue associated with the 4.1 million doses shipped to Wyeth during 2003. We believe the transfer price for the 2003/2004 flu season will be determinable when actual net sales are calculated in 2004, at which time we will record the associated product sales and cost of goods sold.

We receive royalties from licensees, which are based on third-party sales of licensed products or technologies. Royalties are recorded as earned in accordance with the contract terms when third-party results can be reliably measured and collectibility is reasonably assured. We receive royalties from Wyeth based on its sales of FluMist under our worldwide collaborative agreements, as amended. We have not recorded any royalty revenue from Wyeth as of December 31, 2003. The same variables discussed above that affect actual net sales for Wyeth also impact the product royalties that Wyeth is required to remit to us. When the variables are determinable in 2004, we expect to record the product royalties as other revenue.

Revenue from certain guaranteed payments where we continue involvement through a development collaboration or an obligation to supply product is recognized ratably over the development or supply period.

We may record deferred revenues related to milestone payments and other up front payments. Deferred revenue for manufacturing obligations is recognized as product is delivered. Deferred revenue associated with performance milestones is recognized based upon the achievement of the milestones, as defined in the respective agreements, as long as the milestones are substantive and at risk. Revenue under research and development cost reimbursement contracts is recognized as the related costs are incurred.



## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

**Inventory** We capitalize inventory costs associated with marketed products and certain products prior to regulatory approval and product launch, based on management's judgment of probable future commercial use and net realizable value. We could be required to expense previously capitalized costs related to pre-approval or pre-launch inventory upon a change in such judgment, due to a denial or delay of approval by regulatory bodies, a delay in commercialization, or other potential factors. Conversely, our gross margins may be favorably impacted if some or all of the related production costs were expensed prior to the product being available for commercial sale.

We are required to state our inventory at lower of cost or market. In assessing the ultimate realization of inventories, we are required to make judgments as to multiple factors affecting our inventories and compare these with current or committed inventory levels. In the highly regulated industry in which we operate, raw materials, work-in-process and finished goods inventories have expiration dates that must be factored into our judgments about the recoverability of inventory costs. Additionally, if a product's pricing is such that we may not fully recover the cost of inventory, we must consider that in our judgments as well.

FluMist inventories have required a significant amount of judgment since the Acquisition in January 2002. One reason is that the finished FluMist product has a shelf life of nine months. Most of the inventory components for FluMist have expiration dates that range from nine to 24 months. The annual FluMist production cycle begins in October of the year prior to the influenza season in which the product will be consumed. For example, the production cycle for the 2002/2003 season began in October 2001. All production costs for the 2002/2003 season were fully reserved as we assessed the probability of approval by the FDA in time to commercialize the product for the 2002/2003 season was

29

remote. During 2003, we disposed of \$18.7 million of fully reserved inventory related to the 2002/2003 flu season.

Beginning in October 2002, production costs incurred for the 2003/2004 season were partially reserved based on management's assessment of the probability of approval and net realizable value. Approval was received from the FDA on June 17, 2003. At that time, approximately one-half of the annual production costs for the 2003/2004 season had already been fully reserved, \$22.3 million in Q4 2002 and \$19.6 million in Q1 2003. The production cycle for the 2003/2004 season ended in mid-October 2003.

The production cycle for the 2004/2005 season began in mid-October 2003. For all inventory components on hand as of December 31, 2003, we reviewed the following assumptions to determine the amount of any necessary reserves: the expected sales volume; the expected price to be received for the product; potential changes in the influenza strains recommended by the Centers for Disease Control and Prevention for each season's vaccine; and anticipated changes in the manufacturing process. During the fourth quarter of 2003, we determined that additional reserves of approximately \$37.5 million were required to reflect total FluMist inventories at estimated realizable value. These reserves are comprised of the following: raw materials and work-in-process components \$13.3 million; 2003/2004 finished goods inventory \$13.3 million; and 2004/2005 finished goods inventory \$10.9 million.

The table below summarizes the activity within the components of FluMist inventories:

	<u>Gross Inventory</u>	<u>Reserves</u>	<u>Net Inventory</u>
<b><i>FluMist Details</i></b>			
As of December 31, 2002	\$ 62.5	\$ (47.5)	\$ 15.0
Q1 production, net	19.6	(19.6)	
Q1 disposals	(3.1)	3.1	
Q2 production, net	20.7		20.7
Q2 disposals	(13.1)	13.1	
Q3 production, net	18.8	0.1	18.9
Q3 disposals	(2.5)	2.5	
Q4 production, net	20.7	(17.7)	3.0
Q4 disposals	(1.5)	0.5	(1.0)
Q4 valuation adjustments		(20.3)	(20.3)
	<u>122.1</u>	<u>(85.8)</u>	<u>36.3</u>
December 31, 2003	\$ 122.1	\$ (85.8)	\$ 36.3

For our other products, we periodically assess our inventory balances to determine whether net realizable value is below recorded cost. Factors we consider include expected sales volume, production capacity and expiration dates. No significant inventory adjustments were

recorded for the other products.

### **Sales Allowances and Other Sales Related Estimates**

#### *Reductions to Gross Product Sales*

The Company records allowances for discounts, returns, chargebacks and rebates due to government purchasers as reductions to gross product sales. The timing of actual returns, chargebacks and discounts taken, and rebates paid to government purchasers can lag the sale of the product by several periods and varies by state. As such, a significant amount of judgment is required when estimating the impact of sales allowances on gross sales for a reporting period. Our starting point for estimating each of these is our historical experience by product, updated for changes in facts and circumstances as appropriate. Because of the seasonal nature of our largest product, Synagis, our sales discounts, returns, chargebacks and rebates fluctuate throughout the year. If our historical trends are

30

---

not indicative of the future, or our actual sales are materially different from projected amounts, or if our assessments prove to be materially different than actual occurrence, our results could be affected.

We estimate the amount of rebates due to government purchasers quarterly based on historical experience, along with updates, and based on our best estimate of the proportion of sales that will be subject to this reimbursement, largely comprised of Medicaid payments to state governments. During the first quarter of 2003, we lowered our estimate of rebates due to government purchasers to reflect favorable historical experience and a change in our estimate of the proportion of the sales that are subject to reimbursement. As we reviewed our estimates in the second and third quarters of 2003, there were no new significant facts or circumstances that indicated a need for further adjustment. During the fourth quarter of 2003, we became aware of recent efforts by several states to collect rebates for product administered in certain settings for which reimbursement was not sought in the past. After analyzing the situation, we determined that the new facts and circumstances warranted an increase in our estimate of rebates due to government purchasers. As such, we recorded additional reserves for rebates due to government purchasers of approximately \$13.7 million during the fourth quarter of 2003. In addition, we increased our estimate of the proportion of current sales that will be subject to reimbursement, given the change in circumstance.

For the years ended December 31, 2003, 2002, and 2001, allowances for discounts, returns, chargebacks and rebates due to government purchasers resulted in a net reduction to gross product sales of approximately 9% each year. Reserves for discounts, returns, chargebacks and rebates that were accrued and not yet paid as of December 31, 2003 and 2002 were \$51.4 million and \$35.9 million, respectively. Reserves for discounts, returns, and chargebacks are netted against trade receivables and reserves for government reimbursements are included in accrued expenses in the accompanying balance sheets.

#### *Selling, General and Administrative Expenses*

We estimate our co-promotion expense and sales commissions by applying an estimated rate that is based upon an estimate of projected sales for the season to our actual sales for the period. We decreased co-promotion expense by \$2.0 million in 2003 and increased co-promotion expense by \$2.1 million in 2002, resulting from the final reconciliation of net sales for the 2002/2003 and 2001/2002 contract years.

We estimate the level of bad debts as a percentage of gross trade accounts receivable balances outstanding at the end of the period, based upon our assessment of the concentration of credit risk, the financial condition and environment of our customers, and the level of credit insurance we obtain on our customers' balances. Because of the seasonal nature of our largest product, Synagis, our accounts receivable balances fluctuate significantly. Accordingly, our allowance for doubtful accounts also fluctuates. Our accounts receivable balances tend to be highest at the end of December and March, while the September balances are somewhat lower as our selling season is just beginning, and the June balances are negligible, reflecting the close-out of the prior season. For the year ended December 31, 2003, we recorded a \$3.8 million reduction in bad debt expense, largely based on our current assessment of the factors above. For all periods presented, we have reclassified bad debt expense as selling, general and administrative expense in our Consolidated Statements of Operations.

**Income Taxes** We record a valuation allowance to reduce our deferred tax assets to the amount that is anticipated to be realized. We consider future taxable income and ongoing tax planning strategies in assessing the need for the valuation allowance. Should we determine that we were able to realize more than the recorded amounts of net deferred tax assets in the future, our net income would increase in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of the net deferred tax asset in the future, our net income would decrease in the period such determination was made. A tax reserve is recorded when the Company cannot assert

31

that it is probable that a tax position claimed on a return will be sustained upon challenge by the tax authority. Any change in the balance of a tax reserve during the year is treated as an adjustment to current year tax expense.

**Intangible Assets** We have recorded and valued significant intangible assets that we acquired as a result of the Acquisition. We engaged independent valuation experts who reviewed our critical assumptions and assisted us in determining a value for the identifiable intangibles. Of the \$129.4 million of acquired intangible assets, \$90.0 million was assigned to the worldwide collaborative agreement with Wyeth for the development, manufacture, distribution, marketing, promotion, and sale of FluMist. The Company estimated the fair value of the Wyeth agreement using the sum of the probability-adjusted scenarios under the income approach. In applying this method, the Company relied on revenue assumptions, profitability assumptions and anticipated approval dates. The remaining \$39.0 million was assigned to a contract manufacturing agreement with Evans Vaccines Limited. The Company estimated the fair value of the Evans agreement using the cost approach, which is based on the theory that a prudent investor would pay no more for an asset than the amount for which the asset could be replaced. In its analysis, the Company reduced replacement cost for such factors as physical deterioration and functional or economic obsolescence. We review intangible assets for impairment annually or when an event that could result in an impairment occurs. As of December 31, 2003, we have not identified any impairment of the intangible assets, of which \$96.7 million remain unamortized.

During 2003, we reduced goodwill recorded in the Acquisition by \$2.4 million, reflecting additional deferred tax assets for adjustments relating to pre-acquisition items.

## RESULTS OF OPERATIONS

To present our results in the same manner as we view the performance of the business and the resulting underlying trends, we have presented certain expense categories with and without certain Acquisition-related amounts, including: the acquired in-process research and development charge; amortization of intangible assets, compensation expense associated with the assumption and vesting of unvested stock options, retention and severance payments; and the amortization of the premium on convertible subordinated notes. Inclusion of such Acquisition related expenses is consistent with generally acceptable accounting principles. Where we exclude such expenses, we use the term "adjusted."

### Comparison of 2003 to 2002

#### Revenues Product Sales

	<u>2003</u>	<u>2002</u>	<u>Growth</u>
	(In Millions)		
Synagis	\$ 849.3	\$ 671.7	26%
Ethyol	100.2	81.2	23%
FluMist			
Other Products	43.1	38.0	13%
	<u>\$ 992.6</u>	<u>\$ 790.9</u>	<u>25%</u>

Product sales grew 25% in 2003 to \$992.6 million as compared to \$790.9 million in 2002, primarily due to increased sales of Synagis. Of the overall increase in product sales, approximately 16 points of the 25 percentage points were due to an increase in domestic sales volumes, while price increases, net

of increases in sales allowances contributed five points to sales growth. The remaining four points of growth are due to an increase in our international sales.

**Synagis** Synagis accounted for approximately 86% and 85% of our 2003 and 2002 product sales, respectively. We achieved a 21% increase in domestic Synagis sales to \$777.1 million in 2003, up from \$641.3 million in 2002. This growth was largely due to increased sales volume in the United States, which resulted in a 16% increase in domestic units sold. Also aiding growth was a price increase that took effect in June 2003, partially offset by an increase in sales allowances, which are accounted for as a reduction of product sales. Our reported international sales of Synagis to AI, our exclusive distributor of Synagis outside of the United States, more than doubled to \$72.2 million in 2003 compared to \$30.4 million in 2002, driven primarily by a more than two-fold increase in unit volumes over 2002 levels. The increase in unit volume was offset by an decrease in the realized per unit sales price recognized upon delivery of product to AI under the terms of our international distribution agreement. We record Synagis international product sales based on AI's sales price to customers, as defined in the agreement.

**Ethylol** Ethylol accounted for approximately 10% of our product sales in both 2003 and 2002. Domestic Ethylol sales increased 25% to \$94.4 million in 2003, up from \$75.5 million in 2002. This 25% increase is the result of a 15% increase in domestic units sold in 2003 compared to 2002 and a price increase which occurred in August 2003. Our 2003 international sales of Ethylol to our distribution partner, Schering, were consistent with 2002 sales of \$5.7 million. We record Ethylol international product sales based on a percentage of Schering's end-user sales, as defined in our agreement.

**FluMist** During 2003, we shipped 4.1 million doses of FluMist to Wyeth and received payments totaling \$51.9 million. Wyeth is contractually responsible for distributing the product to third parties. At the end of the influenza season, actual net sales for the season will be used to calculate the final transfer price per dose and the amount of product royalties due to MedImmune. Actual net sales consists of any amounts actually received by Wyeth for the sale of FluMist less agreed-upon amounts paid or credited by Wyeth related to the sale of the product such as for returns, promotional discounts, rebates, sales taxes and freight. Prior to the calculation of actual net sales, our ability to recognize revenue is dependent upon our ability to estimate the sales volume for the season and the expected impact of the reduction to sales. As of December 31, 2003, we concluded that the variables associated with the product transfer price were not determinable, largely due to low sales volume and the lack of returns history and comparable redemption rates for rebates for this new product. As a result, we have not recognized the revenue associated with the 4.1 million doses shipped to Wyeth during 2003. We believe the transfer price will be determinable when actual net sales are calculated in 2004, at which time we will record the associated product sales and cost of goods sold.

**Other Products** Sales of other products in 2003, which include sales of CytoGam, NeuTrexin, RespiGam, and by-products that result from the CytoGam manufacturing process, increased \$5.1 million, or 13% compared to last year. The increase was largely due to a 10% increase in our sales of CytoGam.

**Revenues Other Revenues**

Other revenues for 2003 remained consistent with 2002 at \$61.8 million. Other revenues in 2003 are largely comprised of contractual payments received from Wyeth under our collaborative agreement for FluMist. The payments, which amounted to \$45.9 million, related to milestone payments, supply goal payments, and funding for clinical development and marketing programs. We also received \$7.5 million in 2003 from AI for achieving a milestone related to international sales levels of Synagis and we recorded \$3.1 million in revenue under other collaborative agreements. Other revenues in 2002 are comprised largely of \$32.7 million in payments from Wyeth for compensation of 2002 FluMist manufacturing costs and funding for clinical development and marketing programs. In 2002, we also

received \$17.2 million from the sale of excess production capacity to a third party and \$8.7 million in revenue recorded under other collaborative agreements.

We have accounted for major collaborative agreements entered into before January 1, 2002 using the contingency-adjusted performance model and have deferred a portion of the up front and milestone payments received. Based on current estimates, we expect to record the remaining revenues from our collaboration with Schering-Plough Corporation of \$0.8 million ratably over 2004 and 2005.

**Cost of Sales**

2003

2002

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

Historical	Acquisition-Related Adjustments	Adjusted	Historical	Acquisition-Related Adjustments	Adjusted
(in millions)					
\$ 289.8	\$ (2.7)	\$ 287.1	\$ 201.8		\$ 201.8

Cost of sales for 2003 increased 44% to \$289.8 million from \$201.8 million for 2002. Excluding Acquisition-related adjustments in both periods, cost of sales for 2003 increased 42% to \$287.1 million from \$201.8 million in 2002, mainly due to increases in product sales volumes and inventory valuation adjustments for FluMist of \$37.5 million. Gross margins on product sales for 2003 were 71%, down three percentage points from last year, largely due to the valuation adjustments for FluMist inventory. Partially offsetting this decrease were lower costs for CytoGam, and a favorable impact of a value-added tax refund for transfers of Synagis manufactured in Europe.

**Research and Development Expenses**

2003			2002		
Historical	Acquisition-Related Adjustments	Adjusted	Historical	Acquisition-Related Adjustments	Adjusted
(in millions)					
\$ 156.3	\$ (2.6)	\$ 153.7	\$ 147.9	\$ (9.3)	\$ 138.6

Research and development expenses of \$156.3 million in 2003 increased 6% from \$147.9 million in 2002. Excluding Acquisition-related adjustments in both periods, research and development expenses for 2003 were \$153.7 million, up 11% over 2002. The increase is due largely to payments made in 2003 associated with gaining access to new data and technologies including a \$10.0 million payment to Critical Therapeutics, Inc. as part of a new collaboration to co-develop biologic products to treat severe inflammatory diseases. Additionally in 2003, the Company initiated four Phase 2 studies for Vitaxin and agreed to pay \$10.0 million for data from the completed international Phase 3 studies for a liquid formulation of the live, attenuated influenza virus vaccine. This data may have the potential to accelerate the evolution of MedImmune's long-range plans for its intranasally delivered flu vaccine program in the United States.

In 2002, the Company completed several late-stage clinical trials, including Phase 2 clinical trials with siplizumab, and the Phase 3 Synagis clinical trial in congenital heart disease patients that led to approval of an expanded indication by the FDA in September 2003.

34

During 2003, we incurred significant costs related to the development of various products and product candidates. A summary of our more significant research and development efforts is as follows:

Product Candidates	Description	Stage of Development
Vitaxin	Melanoma, Prostate Cancer, Rheumatoid Arthritis, Psoriasis	Phase 2
CAIV-T (liquid FluMist)	A liquid, refrigerator-stable version of FluMist	Phase 3
FluMist-Frozen	Intranasally delivered virus vaccine to prevent influenza infection	Phase 4 and label expansion
Ethylol	Subcutaneous administration in NSCLC patients-reduction of esophogitis and pneumocytis	Phase 2
Numax	Third-generation anti-RSV antibody	Phase 1

Additionally, we have multiple programs in preclinical development.

**Selling, General, and Administrative Expenses**

2003		2002	
Historical	Adjusted	Historical	Adjusted

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

2003			2002		
	Acquisition-Related Adjustments			Acquisition-Related Adjustments	
(in millions)					
\$	340.9	\$ (8.2)	\$	332.7	\$
				(11.9)	\$
					287.7

Selling, general and administrative ("SG&A") expenses increased 14% to \$340.9 million in 2003 compared to \$299.6 million for the 2002 period. Excluding Acquisition-related amounts relating to retention payments, stock option acceleration and stock compensation for unvested stock options assumed and amortization of intangibles, SG&A expenses were \$332.7 million, up 16% over 2002. The increase is largely attributable to increased co-promotion expense, reflective of the increase in Synagis sales. As a percentage of product sales, adjusted SG&A expense decreased to 34% of product sales in the 2003 period from 36% in the 2002 period, due to product sales growing at a faster rate than expenses.

### Other Operating Expenses

2003			2002		
Historical	Acquisition-Related Adjustments	Adjusted	Historical	Acquisition-Related Adjustments	Adjusted
(in millions)					
\$	26.1	\$ (3.1)	\$	23.0	\$
				100.0	\$
				(20.8)	\$
					79.2

Other operating expenses, which reflect manufacturing start-up costs and other manufacturing-related costs, were \$26.1 million in 2003 compared to \$100.0 million in 2002. Adjusted other operating expenses were \$23.0 million for 2003, compared to \$79.2 million in 2002. The decrease is principally due to the shift in the costs of FluMist manufacturing that are capitalized in inventory beginning in the second quarter of 2003, but were expensed as other operating costs in the prior year. Additionally, 2002

other operating expenses include impairment charges of \$12.9 million relating to the write-off of certain plasma manufacturing assets, as the Company outsourced its production of CytoGam during 2002.

### In-Process Research and Development

We incurred charges of \$1,179.3 million in the first quarter of 2002 for the write-off of purchased in-process research and development in conjunction with the Acquisition. The write-off represented the fair value of purchased in-process technologies at the acquisition date, calculated as the sum of probability-adjusted commercial scenarios. This method was based upon management's estimates of the probability of FDA approval and commercial success for FluMist.

### Interest Income and Expense

We earned interest income of \$56.9 million for 2003, compared to \$49.4 million in 2002, reflecting higher cash balances available for investment, partially offset by a decrease in interest rates, which lowered the overall portfolio yield. Interest expense for 2003, net of amounts capitalized, was \$10.3 million, up from \$9.1 million for 2002. Excluding the Acquisition-related amounts of \$2.4 million in 2003 and \$1.8 million in 2002 for the amortization of premium on the 5<sup>1</sup>/<sub>4</sub>% Convertible Subordinated Notes ("the 5<sup>1</sup>/<sub>4</sub>% Notes"), adjusted interest expense increased to \$7.9 million in 2003 from \$7.3 million in 2002, due to interest expense generated by the 1% Notes issued in July 2003.

### Gain (Loss) on Investment Activities

We incurred a gain on investment activities of \$3.4 million for 2003, compared to a loss of \$14.1 million for 2002. The 2003 gain consisted of gains on the sale of our publicly traded equity investments, net of declines in fair value of other investments that were judged to be other than

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

temporary. Investment losses in 2002 consisted primarily of impairment charges on investments related to declines in fair value that were judged to be other than temporary.

### Income Taxes

We recorded income tax expense of \$108.0 million for the year ended December 31, 2003, based on an effective tax rate of 37.1%. Excluding items not deductible for tax purposes, principally the write-off of purchased in-process research and development, the resulting effective tax rate for 2002 was 37.2%.

### Net Earnings / (Loss)

2003			2002		
Historical	Acquisition- Related Adjustments	Adjusted	Historical	Acquisition-Related Adjustments	Adjusted
(in millions)					

\$ 183.2	\$ 9.2	\$ 192.4	\$ (1,098.0)	\$ 1,204.6	\$ 106.6
----------	--------	----------	--------------	------------	----------

Net earnings for 2003 were \$183.2 million, or \$0.73 per share basic and \$0.72 per share diluted, compared to a net loss for 2002 of \$1.1 billion or \$4.40 per share. Excluding the after-tax impact of the Acquisition-related amounts totaling \$9.2 million in 2003 and \$1.2 billion in 2002, adjusted net earnings were \$192.4 million in 2003, or \$0.77 basic and \$0.76 diluted earnings per share and \$106.6 million, or \$0.43 basic and \$0.42 diluted per share in 2002.

Shares used in computing basic and diluted earnings per share in 2003 on a historical basis were 250.1 and 253.8, respectively. Shares used in computing net loss per share on a historical basis for 2002 were 249.6 million. On an adjusted basis, shares used in computing basic and diluted earnings per share

36

in 2003 were 250.1 and 253.8, respectively, while shares used in computing basic and diluted earnings (loss) per share for 2002 were 249.6 million and 252.7 million, respectively.

We do not believe inflation had a material effect on our financial statements.

### 2002 Compared to 2001

#### Revenues Product Sales

	2002	2001	Growth
	(in millions)		
Synagis	\$ 671.7	\$ 518.0	30%
Ethylol	81.2	20.5	296%
Other Products	38.0	43.0	(12)%
	\$ 790.9	\$ 581.5	36%

Product sales grew 36% to \$790.9 million, compared to \$581.5 million in 2001, primarily due to increased sales of Synagis and the impact of reacquiring the domestic marketing rights to Ethylol from ALZA as of October 1, 2001.

**Synagis** Synagis accounted for approximately 85% and 89%, respectively, of our 2002 and 2001 product sales. We achieved a 33% increase in domestic Synagis sales to \$641.3 million in 2002, up from \$481.3 million in 2001. This growth was largely due to increased demand in the

United States, and resulted in a 30% increase in domestic units sold. Also aiding growth was a 3.5% price increase that took effect in June 2002, partially offset by an increase in sales allowances, which were accounted for as a reduction to product sales. Our reported international sales of Synagis decreased 17% to \$30.4 million in 2002 compared to \$36.7 million in 2001, due to a 40% decrease in units sold to AI, our exclusive distributor of Synagis outside of the United States. We believe that the decrease was due to reductions in the inventory stocking levels of AI, rather than reduced product demand by end users. The decrease in unit volume was offset by an increase in the per unit sales price recognized upon delivery of product to AI under the terms of our international distribution agreement. Based on information received from AI, we believe that end-user sales have increased over the 2001 year. We recorded Synagis international product sales based on AI's sales price to customers, as defined in the agreement.

**Ethyol** Ethyol accounted for approximately 10% and 4% of our product sales in 2002 and 2001, respectively. On October 1, 2001 we reacquired domestic marketing rights to Ethyol from ALZA and have since recorded all revenues from domestic sales of Ethyol to wholesalers and distributors. As part of this agreement, no third quarter 2001 supply sales were made to ALZA, and we purchased ALZA's remaining Ethyol inventory at their original purchase price, which was recorded as a reduction to product sales. Beginning April 1, 2002, we pay ALZA a declining royalty through 2011 based on net sales of Ethyol in the United States. Domestic Ethyol sales were \$75.5 million in 2002, as compared to \$14.4 million in 2001. The increase was primarily attributable to a three-fold increase in domestic units sold in 2002 versus the 2001 year, which included nine months of revenues generated under our product supply agreement with ALZA and three months of sales to wholesalers and distributors. Further, two domestic price increases occurred during 2002, including a 9% increase in April 2002 and a 6% increase in September 2002. In addition, 2001 included net returns of \$2.3 million, relating to our assumption of Ethyol marketing rights. Prior to October 1, 2001, we recorded Ethyol domestic product sales based on ALZA's net unit selling price as defined in the agreement. Our international sales of Ethyol to our distribution partner, Schering, were \$5.6 million for 2002, down 7% from the prior year sales of \$6.0 million.

37

---

**Other Products** Sales of other products in 2002, which included sales of CytoGam, NeuTrexin, RespiGam, and by-products that resulted from the CytoGam manufacturing process, decreased \$5.0 million, or 12% compared to 2001. The decrease was due to marginal declines in all of our other product lines.

#### **Revenues Other Revenues**

Other revenues increased 58% to \$61.8 million for 2002 compared to \$39.2 million in 2001. The increase was largely attributable to \$25 million received from Wyeth, our marketing partner for FluMist, for compensation of 2002 FluMist manufacturing costs under amendments to the collaborative agreements. An increase of \$9.7 million in revenues from the sale of excess production capacity to a third party and \$7.7 million in funding for FluMist clinical development and sales and marketing activities from Wyeth also contributed to the growth over 2001. Partially offsetting these increases was a decrease of \$15.5 million in revenue recorded under collaborative agreements, including a \$2.7 million decrease in clinical funding received for our HPV vaccine candidate as we were nearing completion of Phase 1 and 2 clinical trials and our preparation of clinical material.

#### **Cost of Sales**

Cost of sales for 2002 increased 46% to \$201.8 million from \$138.7 million in 2001, due to the increase in sales volumes and additional royalties owed for Synagis, partially offset by manufacturing cost reductions following implementation of an improved manufacturing process at the FMC which enhanced the yields for Synagis. As a result, gross margins for 2002 were down two percentage points to 74% from 76% for the year ended December 31, 2001.

#### **Research and Development Expenses**

Research and development expenses of \$147.9 million in 2002 increased 78% from \$83.0 million in 2001. Excluding Acquisition-related amounts of \$9.4 million in 2002 for retention payments, stock option acceleration and stock compensation expense for unvested options assumed, adjusted research and development expenses were \$138.6 million, up 67% over 2001. This increase was largely due to the on-going activities of MedImmune Vaccines and payments of approximately \$19.0 million to gain access to various technologies and intellectual property to advance our pipeline. The increases were offset by decreases in clinical trial expenses, as several of our clinical trials were either completed, cancelled or delayed during 2002. During 2002, we completed several important clinical trials, including a successful Phase 3 trial for Synagis in children with congenital heart disease and three Phase 2 trials for siplizumab.

During 2002, we completed the preliminary analysis of three Phase 2 trials for siplizumab involving almost 700 psoriasis patients. While the drug appeared to be generally well tolerated and some patients exhibited an improvement in their psoriatic disease, an anti-antibody response (also known as immunogenicity) was observed in the laboratory tests of over 50 percent of the patients. This anti-antibody response did not appear to cause any clinical complications. We also completed two Phase 2 trials of our *E. coli* urinary tract infection vaccine, and have



determined that there was not a sufficient level of efficacy in prevention of urinary tract infections to proceed with additional trials. Our ongoing clinical program also included several product candidates in various phases of evaluation, including a Phase 1 trial in adults using a liquid formulation of Synagis and certain trials for FluMist. Additionally, we had multiple programs in preclinical development.

### **Selling, General, and Administrative Expenses**

Selling, general and administrative ("SG&A") expenses increased 52% to \$299.6 million in 2002 compared to \$196.8 million for the 2001 period. Excluding Acquisition-related amounts of \$11.9 million

38

---

in expense in 2002 relating to retention payments, stock option acceleration and stock compensation for unvested stock options assumed and amortization of intangibles, adjusted SG&A expenses were \$287.5 million, up 46% over 2001. As a percentage of product sales, adjusted SG&A expense increased to 36% of product sales in the 2002 period from 34% in the 2001 period. The increase in this ratio was largely reflective of the impact of the Acquisition and the inclusion of MedImmune Vaccines' ongoing expenses. Additionally, we incurred increased co-promotion expense directly related to the growth in domestic sales of Synagis, higher salaries and sales commissions, as well as increased Synagis marketing expense. SG&A expenses for 2002 also included a \$5.0 million charge associated with the settlement of a contractual dispute in August 2002 regarding an agreement with the Massachusetts Biologic Laboratories of the University of Massachusetts ("MBL") to transfer certain technology relating to the Company's monoclonal antibody manufacturing operations. The comparison to 2001 was favorably impacted as \$13.4 million of expenses related to our accelerated acquisition of Ethyol marketing rights from ALZA was included in SG&A for 2001.

### **Other Operating Expenses**

Other operating expenses, which reflected manufacturing start-up costs and other manufacturing related costs, increased to \$100.0 million in 2002 from \$9.6 million in 2001. Excluding Acquisition-related amounts of \$20.8 million in expense in 2002 relating to stock compensation for unvested stock options assumed and amortization of intangibles, adjusted other operating expenses were \$79.2 million. The increase over 2001 was primarily related to \$56.9 million of pre-production costs and inventory reserves for FluMist. The majority of the cost incurred for FluMist was associated with preparing for the aborted 2002 commercial launch. Additionally, we incurred a \$12.9 million charge for the write-off of CytoGam manufacturing equipment as the Company had outsourced CytoGam production activities as of November 2002. Also included in other operating expense for both periods was excess capacity costs associated with the plasma production section of the FMC.

### **In-Process Research and Development**

We incurred charges of \$1,179.3 million for the year ended December 31, 2002 for the write-off of purchased in-process research and development in conjunction with the Acquisition. The write-off represented the fair value of purchased in-process technologies at the acquisition date, calculated utilizing the sum of the probability-adjusted scenarios under the income approach using a discount rate of 18.7%, and certain in-process research and development projects, primarily FluMist. We do not believe that there would be any alternative future use for the in-process technologies that were written off.

FluMist is a live, attenuated vaccine delivered via a nasal mist for the prevention of influenza. It is a frozen vaccine requiring freezer storage. A liquid influenza vaccine is currently being developed by our partner Wyeth. While there are other flu vaccines currently marketed by other companies, FluMist is, to our knowledge, the only live virus vaccine administered as a nasal mist.

The valuation of the acquired in-process research and development was based upon certain estimates and assumptions by management. The valuation was based upon management's estimates of the probability of FDA approval and commercial success for FluMist. Management's projections were based on assumptions, which may or may not remain valid for the relevant period, including the estimated impact of four "key" factors: price per dose; dose volume; launch date; and the potential failure of the frozen or liquid formulations of the influenza vaccine.

### **Interest Income and Expense**

We earned interest income of \$49.4 million for 2002, compared to \$36.5 million in 2001, reflecting higher cash balances available for investment, largely due to the Acquisition, partially offset by a

39

---

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

decrease in interest rates, which lowered the overall portfolio yield. Interest expense for 2002, net of amounts capitalized, was \$9.1 million, up \$8.5 million over 2001. Excluding the Acquisition-related amount of \$1.8 million for the amortization of premium on the 5<sup>1</sup>/<sub>4</sub>% Notes, adjusted interest expense was \$10.9 million. The increase over 2001 was due to the related interest expense assumed in the Acquisition.

### Loss on Investment Activities

We incurred \$14.1 million in losses on investment activities for 2002. The losses consisted primarily of impairment charges of \$4.5 million on our publicly traded equity investments and \$9.5 million on our minority interest investments related to declines in fair value that were judged to be other than temporary.

### Income Taxes

We recorded income tax expense of \$48.2 million for the year ended December 31, 2002. Excluding items not deductible for tax purposes, principally the write-off of purchased in-process research and development, the resulting effective tax rate was 37.2%. This was compared to tax expense of \$79.5 million recorded for the year ended December 31, 2001, based on an effective tax rate of 34.8%. The higher effective tax rate for 2002 versus 2001 is due to lower credits estimated to be available for research and development activities, including credits earned for orphan drug status of certain research and development activities.

### Net loss

Net loss for the year ended December 31, 2002 was \$1.1 billion, or \$4.40 per share compared to net earnings for the year ended December 31, 2001 of \$149.0 million or \$0.70 basic and \$0.68 diluted earnings per share. Excluding the after-tax impact of the Acquisition-related amounts totaling \$1.2 billion, adjusted net earnings for 2002 were \$106.6 million, or \$0.42 adjusted earnings per diluted share.

Shares used in computing net loss per share in 2002 were 249.6 million. Shares used in computing basic and diluted earnings per share for 2001 were 213.4 million and 220.1 million, respectively. The increase in share count primarily reflects the 34.0 million additional shares issued in conjunction with the Acquisition.

We do not believe inflation had a material effect on our financial statements.

## LIQUIDITY AND CAPITAL RESOURCES

### Sources and Uses of Cash

The Company's capital requirements have been funded from operations, cash and investments on hand, and issuance of common stock and convertible debt. Cash and marketable securities increased 34% to \$1.9 billion at December 31, 2003 from \$1.4 billion at December 31, 2002. This increase is largely due to cash received from the issuance of \$500 million in 1% Notes due in July 2023 as well as cash generated from operations. Working capital increased 49% to \$712.0 million at December 31, 2003 from \$476.8 million at December 31, 2002, primarily due to cash received from the issuance of the 1% Notes.

**Operating Activities** Net cash provided by operating activities increased to \$357.7 million in the year ended December 31, 2003 as compared to \$263.5 million in the comparable 2002 period, primarily as the result of net earnings for the period and the utilization of deferred tax assets to offset our current tax liability. Also affecting cash generated from operating activities were increases in accounts receivable and inventories, partially offset by an increase in accrued co-promotion expense for Synagis.

40

---

**Investing Activities** Cash used for investing activities during 2003 was \$238.3 million, as compared to \$347.0 million in 2002. Cash used for investing activities in 2003 included net additions to our investment portfolio of \$95.0 million and \$112.9 in capital expenditures, primarily for land purchases and construction of the first phase of our new corporate headquarters in Gaithersburg, Maryland, and for the continued expansion of our manufacturing facilities in Pennsylvania, and Speke, the United Kingdom. We also invested \$30.4 million in preferred equity securities and convertible bonds through our venture capital subsidiary.

**Financing Activities** Financing activities generated \$266.2 million in cash for 2003, as compared to \$42.0 million in 2002. Approximately \$44.4 million was received upon the issuance of common stock relating primarily to the exercise of employee stock options in 2003, as

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

compared to \$46.7 million received in 2002, reflecting increased option exercises by employees subsequent to the Acquisition in 2002.

In July 2003, the Company completed the issuance of \$500 million of 1% Notes due 2023. Net proceeds to the Company were \$489.4 million, net of expenses, underwriters' discounts and commissions. At the time of issuance, we stated our intent to use a portion of the proceeds from the 1% Notes to repurchase shares of our common stock under the stock repurchase program, and for general corporate purposes, which may include the retirement of existing debt obligations, possible acquisitions or other external growth opportunities. As of December 31, 2003, we have repurchased and retired \$32.4 million principal amount of the 5<sup>1</sup>/<sub>4</sub>% notes at a cost of \$33.1 million. A gain of \$0.5 million was recorded in accordance with the transactions, representing the acceleration of the premium recorded on these notes in accordance with the Acquisition.

In July 2003, our Board of Directors authorized the repurchase, over a two-year period, of up to \$500 million of the Company's common stock in the open market or in privately negotiated transactions, pursuant to terms management deems appropriate and at such times it may designate. Under the stock repurchase program, we repurchased 6.2 million shares of our common stock at a total cost of \$229.8 million, or an average cost of \$36.83 per share through December 31, 2003. The Company also entered into a 10b5-1 trading plan to repurchase shares in the open market during those periods each quarter when trading in our common stock is restricted under our insider trading policy. Of the shares repurchased, approximately 0.7 million shares were purchased under the 10b5-1 trading plan. As of February 29, 2004, we had not purchased any additional shares since October 7, 2003, but intend to resume repurchasing during 2004. The Company will hold repurchased shares as treasury shares and intends to use them for general corporate purposes, including but not limited to acquisition-related transactions and for issuance upon exercise of outstanding stock options.

We expect to make capital expenditures in the range of \$100-125 million during 2004 for projects such as continued construction of our corporate headquarters in Gaithersburg, Maryland and FluMist manufacturing facilities in Speke, the United Kingdom, construction of a new pilot plant in Gaithersburg, Maryland, and land purchases relating to future expansion phases of our headquarters facility. The Company anticipates these projects will be funded from cash generated from operations and investments on hand. We expect to take occupancy of the first phase of our headquarters facility, a complex of approximately 220,000 square feet, in March 2004. The majority of our existing space in Gaithersburg is leased through 2006, a portion of which will be offered for sublease. There can be no guarantee that we will be successful in subleasing the space.

The Company's 5<sup>1</sup>/<sub>4</sub>% Notes are redeemable beginning in February 2004. The Company intends to redeem the entire remaining amount of the issue at approximately 103% of its principal amount in the first quarter of 2004. The redemption is expected to be financed from cash and investments on hand.

41

**Contractual Obligations and Commitments** The following table summarizes our contractual obligations and commitments that will require significant cash outlays in the future:

	<u>Total</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>Beyond</u>
<b>Contractual Obligations</b>							
Long-term debt(1)	\$ 675.7	\$ 0.9	\$ 1.0	\$ 1.0	\$ 1.3	\$ 168.1	\$ 503.4(2)
Facilities leases	54.3	8.8	6.5	4.5	2.8	2.5	29.2
Purchase obligations	136.1	59.2	20.4	11.5	7.5	7.5	30.0
Evans liability	26.8	3.9	22.9				
	<u>892.9</u>	<u>72.8</u>	<u>50.8</u>	<u>17.0</u>	<u>11.6</u>	<u>178.1</u>	<u>562.6</u>
<b>Other Commercial Commitments</b>							
Standby letters of credit	\$ 2.2	\$ 2.2	\$	\$	\$	\$	\$
Obligations under Collaborative Agreements(3)	16.6	7.5	2.3	1.9	1.1	0.8	3.0
	<u>18.8</u>	<u>9.7</u>	<u>2.3</u>	<u>1.9</u>	<u>1.1</u>	<u>0.8</u>	<u>3.0</u>

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

- (1) The 2008 amount includes the aggregate principal amount of the 5<sup>1</sup>/<sub>4</sub>% Notes. They are recorded at a premium on the balance sheet, which represents their fair value at the time of the Acquisition. These notes are due in 2008; however, in February 2004 the Board of Directors approved their redemption, which is expected to be completed by March 31, 2004.
- (2) The 1% Notes can be put to MedImmune by the holders for cash in 2006.
- (3) We participate in a number of research and development collaborations to develop and market certain technologies and products. The amounts indicated as obligations under collaborative agreements represent committed funding obligations to our collaborative partners under our various development programs. The amounts do not include any milestone payments or royalty payments related to these collaborations since the amount, timing, and likelihood of the payments is unknown as they are dependent on the occurrence of future events that may or may not occur.

42

### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The following discussion about our risk-management activities includes "forward-looking statements" that involve risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements.

Our primary market risks as of December 31, 2003 are the exposures to loss resulting from changes in interest rates, foreign currency exchange rates, and equity prices. Market risk exposure with respect to interest rates and equity prices exceeds that of December 31, 2002 due to the increase in the size of our investment portfolio.

As of December 31, 2003, our excess cash balances are primarily invested in marketable debt securities with investment grade credit ratings. Substantially all of our cash and cash equivalents and short-term and long-term investments are held in custody by three major U.S. financial institutions. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. Our investments include U.S. corporate debt securities, which include commercial paper and notes, international bank debt securities, and U.S. government and agency notes and bonds. The maturities range from one month to seven years. Our investment guidelines are intended to limit the amount of investment exposure as to issuer, maturity, and investment type. The fair value of these investments is sensitive to changes in interest rates. Further, interest income earned on variable rate debt securities is exposed to changes in the general level of interest rates.

The following table presents principal cash flows and weighted average interest rates by expected maturity dates for each class of debt security with similar characteristics (in millions):

	2004	2005	2006	2007	2008	2009	2010	Total	Fair Value
U.S. Gov't and Agencies	\$ 30.0	\$	\$ 11.0	\$ 15.0	\$ 31.9	\$ 15.0	\$	\$ 102.9	\$ 109.1
Interest Rate	3.8%		5.5%	4.8%	4.4%	6.5%			
Corp. Debt Securities	\$ 196.9	\$ 153.4	\$ 183.2	\$ 208.3	\$ 264.3	\$ 112.9	\$ 15.4	\$ 1,134.4	\$ 1,214.5
Interest Rate	5.8%	6.6%	5.6%	5.5%	4.1%	6.1%	7.5%		
Foreign Bank Debt Securities	\$ 7.5	\$ 8.0	\$ 23.0	\$	\$ 2.8	\$	\$	\$ 41.3	\$ 45.3
Interest Rate	4.0%	4.1%	7.4%		5.9%				

We are exposed to equity price risks and risk of impairment related to our minority interest investments. MedImmune Ventures, Inc., the Company's wholly-owned venture capital subsidiary, manages the Company's current portfolio of minority interest investments and endeavors to make additional investments in public or private biotechnology companies focused on discovering and developing human therapeutics. MedImmune Ventures will invest primarily in areas of strategic interest to the Company, including infectious disease, immunology and oncology. The cost basis of MedImmune Venture's investment holdings was \$39.2 million as of December 31, 2003, and is expected to increase in the future as it continues to invest in accordance with its investment strategy.

MedImmune Venture's minority interest investments are subject to adjustment for other-than-temporary impairments. We recognize impairment charges in the consolidated statements of operations when a decline in the fair value of an investment falls below its cost value and is judged to be other than temporary. We consider various factors in determining whether we should recognize an impairment charge, including: the length of time and extent to which the fair value has been less than our cost basis; the financial condition and near-term prospects of the issuer; fundamental changes to the business prospects of the investee; share prices of subsequent offerings; and our intent and ability to hold the

investment for a period of time sufficient to allow for any anticipated recovery in market value. During 2003 and 2002, the Company recorded impairment losses of \$1.7 million and \$14.0 million, respectively, based on the duration and magnitude of the declines in fair value, as well as

the financial condition and near-term prospects of the investee companies. We did not incur any impairment losses during the year ended December 31, 2001. We expect the volatility in the fair value of our minority investments to continue and, thus, the value assigned to the investments could change significantly from period to period.

As of December 31, 2003, the MedImmune Venture's portfolio included approximately 1.8 million shares of common stock in two publicly traded companies with which the Company previously formed strategic alliances. In accordance with our investment strategy, we intend to liquidate our holdings in these equity securities over a period of approximately one year, now that our business objectives have been reached. To hedge the risk of market fluctuations relative to these investments, we entered into equity derivative contracts during the second half of 2003, which have been designated as cash flow hedges. As of December 31, 2003, the unrealized gain on the marketable equity securities related to this hedge was \$13.2 million, while the fair value of the derivative contracts was a liability of \$3.5 million, resulting in a net unrealized gain on the hedging transaction. During the fourth quarter of 2003, we recognized net gains on sales of a portion of the holdings of \$4.4 million.

The remainder of MedImmune Venture's portfolio as of December 31, 2003 consists of minority interest investments in privately held biotechnology companies. The investments are maintained on the cost or equity method of accounting, according to the facts and circumstances of the individual investment. For investments carried on the equity method, the Company's proportionate share of the investee's gains or losses is recorded on a quarterly basis. As of December 31, 2003, the investments had a cost basis of \$36.7 million.

Following the Acquisition, the Company's subsidiary, MedImmune Vaccines, assumed the obligation for \$200.0 million in 5<sup>1</sup>/<sub>4</sub>% Notes due 2008. These notes were recorded at their fair value of \$211.4 million, based on quoted market prices as of January 10, 2002, the acquisition date. Interest is payable semi-annually in arrears in cash on February 1 and August 1 each year. Changes in interest rates do not affect interest expense incurred because they bear interest at fixed rates. During 2003, the Company purchased \$32.4 million principal amount of the 5<sup>1</sup>/<sub>4</sub>% Notes in the open market for \$33.1 million, resulting in a net gain of \$0.5 million on early extinguishment recorded to earnings. As of December 31, 2003, the notes are convertible into an aggregate of 2.9 million shares of the Company's common stock, based on a conversion price of \$58.14, at any time on or before February 1, 2008. The Company may redeem the 5<sup>1</sup>/<sub>4</sub>% Notes beginning in February 2004, at redemption prices declining from 103% of their principal amount in 2004 to 100% in 2008, plus accrued interest. The estimated fair value of these notes at December 31, 2003, based on quoted market prices, was \$173.4 million.

During July 2003, we issued \$500 million of convertible notes due 2023. These notes bear interest at 1.0% per annum payable semi-annually in arrears. Beginning with the six-month interest period commencing July 15, 2006, if the average trading price of these notes during specified periods equals or exceeds 120% of the principal amount of such notes, we will pay contingent interest equal to 0.175% per six-month period of the average trading price per \$1,000 of the principal amount during such periods. As a result, if the market value of these notes appreciates significantly in the future, we could be obligated to pay significant amounts of contingent interest beginning in 2006. The estimated fair value of the 1% Notes at December 31, 2003, based on quoted market prices, was \$475.0 million.

Changes in interest rates do not affect interest expense incurred on our remaining outstanding indebtedness of \$8.0 million and \$8.8 million at December 31, 2003 and 2002, respectively, because the borrowings are in the form of notes that bear interest primarily at fixed rates. The estimated fair value of the remaining long-term debt at December 31, 2003 and 2002, based on quoted market prices or discounted cash flows at currently available borrowing rates, was \$8.4 million and \$9.3 million, respectively. Maturities for all long term debt for the next five years are as follows: 2004, \$0.9 million; 2005, \$1.0 million; 2006, \$1.0 million; 2007, \$1.3 million; and 2008, \$168.1 million.

Expenditures relating to our manufacturing operations in the United Kingdom and the Netherlands are paid in local currency. We have not hedged our expenditures relating to these manufacturing operations; therefore, foreign currency exchange rate fluctuations may result in increases or decreases in the amount of expenditures recorded. Additionally, certain of our distribution agreements outside the United States provide for us to be paid based upon sales in local currency. As a result, changes in foreign currency exchange rates could adversely affect the amount we expect to collect under these agreements.

The Company has entered into a supplemental manufacturing contract denominated in Euros. Fluctuations in the Euro-U.S. Dollar exchange rate may lead to changes in the U.S. Dollar cost of manufacturing. To reduce the risk of unpredictable changes in these costs, the

Company may, from time to time, enter into forward foreign exchange contracts. Currently, we have firm commitments with BI for planned production and fill/finish for approximately 78 million Euros. As of December 31, 2003, the Company did not have any open foreign exchange forward contracts. As of December 31, 2002, the Company had outstanding forward contracts to purchase 1.1 million Euros, all expiring within one year. Fair value of the outstanding contracts at December 31, 2002 was \$0.3 million. During 2002, we entered into foreign exchange forward contracts to purchase 12.5 million British Pounds (GBPs) to fund payments due under construction contracts denominated in GBPs. The contracts were originally designated as cash flow hedges, but were later determined to be ineffective and subsequently cancelled, resulting in a net gain of \$0.2 million recorded to the income statement.

---

**ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**
**MedImmune, Inc.**
**Consolidated Balance Sheets**
**(in thousands)**

	<b>December 31, 2003</b>	<b>December 31, 2002</b>
	<b>_____</b>	<b>_____</b>
<b>ASSETS:</b>		
Cash and cash equivalents	\$ 515,502	\$ 130,056
Marketable securities	272,765	396,882
Trade receivables, net	161,229	113,774
Inventory, net	91,703	59,963
Deferred tax assets	29,322	25,735
Other current assets	32,233	17,023
	<b>_____</b>	<b>_____</b>
Total Current Assets	1,102,754	743,433
Marketable securities	1,111,882	896,118
Property and equipment, net	273,597	183,992
Deferred tax assets, net	151,280	222,038
Intangible assets, net	96,694	113,275
Goodwill	13,614	15,970
Other assets	44,849	13,463
	<b>_____</b>	<b>_____</b>
Total Assets	\$ 2,794,670	\$ 2,188,289
	<b>_____</b>	<b>_____</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY:</b>		
Accounts payable	\$ 22,116	\$ 19,773
Accrued expenses	218,035	157,359
Product royalties payable	81,808	74,048
Advances from Wyeth	51,910	
Deferred revenue	813	6,789
Other current liabilities	16,033	8,684
	<b>_____</b>	<b>_____</b>
Total Current Liabilities	390,715	266,653
Long-term debt	681,223	217,554

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

	December 31, 2003	December 31, 2002
Obligations to Evans	21,627	24,755
Other liabilities	1,887	2,093
<b>Total Liabilities</b>	<b>1,095,452</b>	<b>511,055</b>
Commitments and Contingencies		
<b>SHAREHOLDERS' EQUITY:</b>		
Preferred stock, \$.01 par value; authorized 5,525 shares; none issued or outstanding		
Common stock, \$.01 par value; authorized 420,000 shares; outstanding 248,036 at December 31, 2003 and 251,262 at December 31, 2002	2,543	2,513
Paid-in capital	2,673,059	2,613,075
Deferred compensation	(1,379)	(6,823)
Accumulated deficit	(772,936)	(956,140)
Accumulated other comprehensive income	27,733	24,609
	1,929,020	1,677,234
Less: Treasury stock at cost; 6,239 shares as of December 31, 2003 and no shares at December 31, 2002	(229,802)	
<b>Total Shareholders' Equity</b>	<b>1,699,218</b>	<b>1,677,234</b>
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 2,794,670</b>	<b>\$ 2,188,289</b>

The accompanying notes are an integral part of these financial statements.

**MedImmune, Inc.**

**Consolidated Statements of Operations**

(in thousands, except per share data)

	For the year ended December 31,		
	2003	2002	2001
<b>Revenues</b>			
Product sales	\$ 992,554	\$ 790,906	\$ 581,514
Other revenue	61,780	61,778	39,150
<b>Total revenues</b>	<b>1,054,334</b>	<b>852,684</b>	<b>620,664</b>
<b>Costs and Expenses</b>			
Cost of sales	289,756	201,841	138,707
Research and development	156,318	147,942	82,985
Selling, general, and administrative	340,902	299,562	196,826

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

For the year ended December 31,

Other operating expenses	26,138	100,029	9,606
Acquired in-process research and development		1,179,321	
<b>Total expenses</b>	<b>813,114</b>	<b>1,928,695</b>	<b>428,124</b>
Operating income (loss)	241,220	(1,076,011)	192,540
Interest income	56,854	49,355	36,516
Interest expense	(10,335)	(9,110)	(590)
Gain (loss) on investment activities	3,438	(14,074)	
Earnings (loss) before income taxes	291,177	(1,049,840)	228,466
Provision for income taxes	107,973	48,175	79,506
<b>Net earnings (loss)</b>	<b>\$ 183,204</b>	<b>\$ (1,098,015)</b>	<b>\$ 148,960</b>
<b>Basic earnings (loss) per share</b>	<b>\$ 0.73</b>	<b>\$ (4.40)</b>	<b>\$ 0.70</b>
Shares used in calculation of basic earnings (loss) per share	250,144	249,625	213,378
<b>Diluted earnings (loss) per share</b>	<b>\$ 0.72</b>	<b>\$ (4.40)</b>	<b>\$ 0.68</b>
Shares used in calculation of diluted earnings (loss) per share	253,817	249,625	220,101

The accompanying notes are an integral part of these financial statements.

47

MedImmune, Inc.

Consolidated Statements of Cash Flows

(in thousands)

For the year ended December 31,

	2003	2002	2001
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net earnings(loss)	\$ 183,204	\$ (1,098,015)	\$ 148,960
Adjustments to reconcile net earnings (loss) to net cash provided by operating activities:			
Acquired in-process research and development		1,179,321	
Deferred taxes	86,978	50,806	76,398
Deferred revenue	(5,976)	(7,050)	(21,430)
Depreciation and amortization	37,662	36,820	9,124
Advances from Wyeth	51,910		
Amortization of premium (discount) on marketable securities	14,821	9,752	(2,024)
Amortization of deferred compensation	4,046	19,228	
Amortization of bond premium	(3,130)	(1,819)	
(Gain) loss on investment activities	(3,438)	14,074	



Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

	<b>For the year ended December 31,</b>		
Impairment of long-lived assets		14,058	
Increase in sales allowances	10,877	17,427	9,599
Losses on writedowns of inventory	58,965	44,671	2,910
Change in restructuring liability for cash employee termination costs	(661)	(5,142)	
Other	3,693	796	(138)
Increase (decrease) in cash due to changes in assets and liabilities:			
Trade receivables	(36,743)	3,944	(2,866)
Inventory	(86,590)	(43,959)	(6,559)
Other assets	(14,507)	(2,220)	2,697
Accounts payable and accrued expenses	45,321	4,627	25,451
Product royalties payable	7,760	26,328	7,166
Other liabilities	3,469	(105)	1,627
<b>Net cash provided by operating activities</b>	<b>357,661</b>	<b>263,542</b>	<b>250,915</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Investments in securities available for sale	(659,914)	(1,008,936)	(842,589)
Maturities of securities available for sale	345,611	467,254	312,954
Proceeds from sales of securities available for sale	219,305	137,393	371,230
Net cash acquired in acquisition of Aviron		146,853	
Capital expenditures, net of capitalized interest	(112,940)	(80,871)	(18,258)
Investments in strategic alliances	(30,405)	(8,735)	(11,499)
<b>Net cash used in investing activities</b>	<b>(238,343)</b>	<b>(347,042)</b>	<b>(188,162)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Proceeds from issuance of common stock	44,409	46,664	24,339
Share repurchases	(229,802)		
Proceeds of 1% Notes, net of issuance costs	489,361		
Debt prepayments	(33,124)		
Repayments on long-term obligations	(4,694)	(4,639)	(742)
<b>Net cash provided by financing activities</b>	<b>266,150</b>	<b>42,025</b>	<b>23,597</b>
Effect of exchange rate changes on cash	(22)	276	(69)
Net increase (decrease) in cash and cash equivalents	385,446	(41,199)	86,281
Cash and cash equivalents at beginning of year	130,056	171,255	84,974
Cash and cash equivalents at end of year	\$ 515,502	\$ 130,056	\$ 171,255
<b>Supplemental cash flow data:</b>			
Cash paid during the year for interest	\$ 13,701	\$ 11,013	\$ 559
Cash paid (received) paid during the year for income tax payments (refunds)	\$ 32,740	\$ (2,320)	\$ 505

**Supplemental schedule of noncash investing and financing activities:**

During January 2002, the Company acquired 100% of the outstanding capital stock of Aviron through an exchange offer and merger transaction. The Company exchanged approximately 34.0 million of its common shares for all of the outstanding shares of Aviron common stock and assumed Aviron's outstanding options and warrants, for which approximately 7.0 million additional shares of the Company's common stock are issuable. The estimated fair value of the net assets acquired was \$1,635.1 million, and included \$1,179.3 million of acquired research and development assets that were charged to current period results at the date of acquisition and \$211.4 million of 5<sup>1</sup>/<sub>4</sub>% notes due in 2008.

## MedImmune, Inc.

## Consolidated Statements of Shareholders' Equity

(in thousands)

	Common Stock, \$.01 par		Paid-in Capital	Deferred Compensation	Accumulated Earnings (Deficit)	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total
	Shares	Amount					Shares	Amount	
<b>Balance, December 31, 2000</b>	211,348	\$ 2,113	\$ 842,815		\$ (7,085)	5,739	\$	\$	843,582
Net earnings					148,960				148,960
Change in foreign currency translation adjustment						(216)			(216)
Unrealized gain on investments, net of tax						3,071			3,071
Unrealized gain on hedged inventory purchases, net of tax						32			32
Comprehensive income									151,847
Common stock options exercised	3,092	31	22,818						22,849
Issuance of common stock under the employee stock purchase plan	44	1	1,489						1,490
Tax benefit associated with the exercise of stock options			24,505						24,505
<b>Balance, December 31, 2001</b>	214,484	2,145	891,627		141,875	8,626			1,044,273
Net loss					(1,098,015)				(1,098,015)
Change in foreign currency translation adjustment						778			778
Unrealized gain on investments, net of tax						15,079			15,079
Unrealized gain on hedged inventory purchases, net of tax						126			126
Comprehensive loss									(1,082,032)
Common stock options exercised	2,663	27	42,673						42,700
	163	2	3,962						3,964

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

Common Stock, \$.01								
par								
Issuance of common stock under the employee stock purchase plan								
Tax benefit associated with the exercise of stock options			14,804					14,804
Shares issued related to the acquisition of Aviron	339	1,664,412		(39,454)				1,625,297
Amortization of deferred compensation for the vesting of stock options	33,952			19,228				19,228
Reversal of deferred compensation for cancellation of stock options		(4,403)		4,403				
Decrease in restructuring liability for amortization of deferred compensation for the vesting of stock options				9,000				9,000
<b>Balance, December 31, 2002</b>	<b>251,262</b>	<b>2,513</b>	<b>2,613,075</b>	<b>(6,823)</b>	<b>(956,140)</b>	<b>24,609</b>		<b>1,677,234</b>
Net earnings					183,204			183,204
Change in foreign currency translation adjustment						1,651		1,651
Unrealized gain on investments, net of tax						3,713		3,713
Unrealized loss on cash flow hedges, net of tax						(2,240)		(2,240)
Comprehensive income								186,328
Common stock options exercised	2,807	28	39,866					39,894
Issuance of common stock under the employee stock purchase plan	206	2	4,781					4,783
Repurchases of common stock					(6,239)	(229,802)		(229,802)
Tax benefit associated with the exercise of stock options			16,023					16,023
Amortization of deferred compensation for the vesting of stock options				4,758				4,758
Reversal of deferred compensation for cancellation of stock options			(686)	686				
<b>Balance, December 31, 2003</b>	<b>254,275 \$</b>	<b>2,543 \$</b>	<b>2,673,059 \$</b>	<b>(1,379) \$</b>	<b>(772,936) \$</b>	<b>27,733 \$</b>	<b>(6,239) \$</b>	<b>(229,802) \$ 1,699,218</b>

The accompanying notes are an integral part of these financial statements

---

**MEDIMMUNE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****1. ORGANIZATION**

MedImmune, Inc., a Delaware corporation (together with its subsidiaries, the "Company"), is a biotechnology company headquartered in Gaithersburg, Maryland. During January 2002, the Company completed its acquisition of Aviron, subsequently renamed MedImmune Vaccines, Inc., a biopharmaceutical company headquartered in Mountain View, California, through an exchange offer and merger transaction (the "Acquisition"). The Acquisition was accounted for as a purchase, and the results of operations of MedImmune Vaccines are included in the results of the Company effective January 10, 2002 (see Note 3).

The Company currently actively markets four products, Synagis, Ethyol, CytoGam, and FluMist, and maintains a diverse research and development pipeline. The Company is focused on developing vaccines and antibodies that address significant medical needs in the areas of infectious diseases, immunology and oncology.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

Significant accounting policies applied in the preparation of these financial statements are as follows:

**Basis of Presentation** The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

**Seasonality** The Company's largest revenue-generating product, Synagis, is used to prevent RSV disease in high-risk infants. RSV is most prevalent in the winter months in the northern hemisphere. Because of the seasonal nature of RSV, limited sales, if any, of Synagis are expected during the second and third quarters of any calendar year, causing results to vary significantly from quarter to quarter. Sales of Synagis comprised approximately 86%, 85% and 89% of total product sales for the years ended December 31, 2003, 2002, and 2001, respectively.

FluMist is a nasally delivered live attenuated vaccine used to prevent influenza, which is most prevalent in the fall and winter months. The majority of FluMist sales are expected to occur between October and January because of the seasonal nature of influenza, causing results to vary significantly from quarter to quarter.

**Cash, Cash Equivalents and Marketable Securities** The Company considers all highly liquid instruments purchased with a maturity of three months or less at date of purchase to be cash equivalents. Investments in marketable securities consist principally of debt securities of U.S. corporations, including commercial paper and notes, debt securities of international banks, and U.S. Government and Agency notes and bonds. Investments with maturities of three to 12 months from the balance sheet date are considered current assets, while those with maturities in excess of one year are considered non-current assets. The securities are held for an unspecified period of time and may be sold to meet liquidity needs and therefore are classified as available-for-sale. Accordingly, the Company records these investments at fair value, with unrealized gains and losses on investments reported, net of tax, as a component of other comprehensive income.

Substantially all of the Company's cash and cash equivalents, and short-term and long-term investments, are held in custody by three major U.S. financial institutions. The majority of the Company's cash equivalents consist of U.S. Government Federal Agency Securities, short-term marketable securities, and overnight repurchase agreements. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon

---

demand and, therefore, bear minimal risk. The Company's short-term and long-term investments generally consist of marketable securities with investment grade credit ratings and deposits with major banks. The Company's investment guidelines are intended to limit the amount of investment exposure as to issuer, maturity, and investment type. Maturities generally range from one month to seven years. The fair values of these investments are sensitive to changes in interest rates and the credit-worthiness of the security issuers. Further, interest income earned on variable rate debt securities is exposed to changes in the general level of interest rates.

**Minority Interest Investments** The Company's wholly-owned venture capital subsidiary, MedImmune Ventures, Inc., manages the Company's current portfolio of minority interest investments and endeavors to make additional investments in public or private biotechnology companies, primarily in areas of strategic interest to the Company. The investments are maintained on the cost or equity method of accounting, according to the facts and circumstances of the individual investment. Under either method, the investments are subject to adjustment for other-than-temporary impairments. Additionally, for investments carried on the equity method, the Company's proportionate share of the investee's gains or losses is recorded on a quarterly basis. Minority interest investments in publicly traded companies are categorized as available-for-sale securities. Due to the highly volatile share prices of these investments, the investments are subject to unrealized holding gains or losses.

During 2003, the Company determined the decline in fair value of one investment was other than temporary, based on the financial condition and near-term prospects of the investee company. During 2002, the Company determined that the declines in fair value below the basis of certain of its minority interest investments were other than temporary, based primarily on the duration and magnitude of the declines in fair value, largely due to the downward movement in the capital markets, as well as the financial condition and near-term prospects of the investee companies. For the years ended December 31, 2003 and December 31, 2002, the Company recorded impairment losses of \$1.7 million and \$14.0 million, respectively, to write-down the cost basis of its minority interest investments to estimated fair value.

**Fair Value of Financial Instruments** The carrying amount of financial instruments, including cash and cash equivalents, trade receivables, contracts receivable, other current assets, accounts payable, and accrued expenses, approximate fair value as of December 31, 2003 and 2002 due to the short maturities of these instruments.

**Concentration of Credit Risk** The Company sells its products primarily to a limited number of pharmaceutical wholesalers and distributors without requiring collateral. The Company periodically assesses the financial strength of these customers and establishes allowances for anticipated losses when necessary. The Company also minimizes its credit risk from these customers by purchasing insurance coverage for certain customers. As of December 31, 2003, trade accounts receivable included four customers that each accounted for 27%, 16%, 15% and 12%, of net trade accounts receivable, respectively. As of December 31, 2002, trade accounts receivable included three customers that each accounted for 22%, 21% and 19% of net trade accounts receivable, respectively.

**Inventory** Inventories are stated at the lower of cost or market, and consist of currently marketed products and may include certain product candidates awaiting regulatory approval. Cost is determined using the first-in, first-out method. With respect to inventory for product candidates, the Company considers the probability that revenues will be obtained from the future sale of the related inventory together with the status of the product candidate within the regulatory approval process. Currently, the Company does not have any inventory for product candidates. The Company records an inventory reserve for estimated obsolescence, excess or unmarketable inventory in an amount equal to the difference between the cost of inventory and its estimated realizable value based upon assumptions about future demand and market conditions.

**Product Sales** The Company recognizes revenue on product sales when persuasive evidence of an arrangement exists, delivery has occurred, the sales price is fixed or determinable, and collectibility is probable. These criteria are generally met upon receipt of the product by customers. As more fully explained in the "Critical Accounting Estimates" section of Management's Discussion and Analysis, no FluMist transfer price or royalty revenue was recognized in 2003, as the Company determined the amounts were not fixed or determinable.

In certain of the Company's international distribution agreements, the compensation received by the Company from its partner is variable based, in part, on the end-user sales price. When all of the other revenue criteria have been met, the Company recognizes revenue to the extent that the customer has an obligation to pay, the customer has limited or no control over the end-user sales price and, accordingly, any subsequent adjustments to the recorded revenue are not expected to be significant. Subsequent adjustments to recorded revenue that result from variances between amounts previously invoiced and the total sales price received are recorded as an adjustment to product sales in the quarter in which they become known.

Product sales are recorded net of allowances for estimated chargebacks, returns, discounts, and government rebates. Both in the United States and elsewhere, sales of pharmaceutical products depend on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. The Company estimates the portion of its sales that will be covered by government insurance and records allowances at a level that management believes is sufficient to cover estimated requirements for reimbursements. Allowances for discounts, returns, chargebacks, and bad debts, which are netted against accounts receivable, totaled \$12.8 million and \$18.1 million at December 31, 2003 and 2002, respectively. Allowances for government reimbursements were \$42.4 million and \$26.2 million as of December 31, 2003 and 2002, respectively, and are included in accrued expenses in the accompanying balance sheets.

#### **Other Revenues**

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

**Contract Revenues** In December 1999, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 101 ("SAB 101"). SAB 101 summarizes certain of the SEC's views in applying accounting principles generally accepted in the United States of America to certain revenue transactions in financial statements. The Company implemented SAB 101 as of January 1, 2000, which affected amounts previously recognized as revenue relating to up front payments or milestone payments received by the Company in years prior to 2000 under arrangements for which performance obligations related to the up front or milestone payments had been met, but for which the Company is contractually obligated to perform additional research and development activities or other activities in future periods.

For contracts executed prior to January 1, 2002, contract revenues are recognized during each period in accordance with the contingency-adjusted performance model. Revenue from non-refundable up front license fees, milestones, or other payments where we continue involvement through a development collaboration is recognized on a straight-line basis over the development period, unless there are specific output measures that indicate a different basis is more appropriate.

In connection with the Company's adoption of SAB 101 using the contingency-adjusted performance model, a portion of the up front and milestone payments received under collaborative agreements with Abbott, ALZA, GSK, and Schering were deferred and are being recognized over the period of fulfillment of the contractual obligations. As of December 31, 2003 and December 31, 2002, the remaining balance of deferred revenue with respect to amounts received under these agreements was \$0.8 million and \$3.9 million, respectively.

For new contracts executed or acquired after January 1, 2002, the Company changed its accounting method for contract revenues to use the milestone payment method when all milestones to be received

52

---

under contractual arrangements are determined to be substantive, at-risk and the culmination of an earnings process. Substantive milestones are payments that are conditioned upon an event requiring substantive effort, when the amount of the milestone is reasonable relative to the time, effort and risk involved in achieving the milestone and when the milestones are reasonable relative to each other and the amount of any up front payment. If all of these criteria are not met, then the Company will use the contingency-adjusted performance model. The change in accounting principle was made to more closely reflect the essence of the Company's contractual obligations with collaborative partners. Also, the new method is prevalent in the industry in which the Company operates. The effect on net loss and net loss per share for the year ended December 31, 2002 (the year of adoption) is not material.

**Miscellaneous Revenues** Other revenues include licensing fees, grant income, royalty income, corporate funding, and reimbursement of expenses under research and other collaborative agreements. These revenues are recognized on the earlier of when the payments are received or when collection is assured and only when no further performance obligations exist.

**Royalty Expense** Product royalty expense is recognized as a cost of sales concurrently with the recognition of product revenue, net of allowances for estimated chargebacks, returns, discounts, and government rebates, based on a contractually stipulated royalty percentage. Any adjustments to royalty expense that result from variances between estimated and actual net sales are recorded as an adjustment to expense in the quarter they become known.

### **Research and Development Expenses**

**Licensing Fees** In the normal course of business, the Company enters into collaborative research and development and in-licensing agreements to acquire access to technology. These collaborative agreements usually require the Company to pay up front fees and milestone payments, some of which are significant. All up front payments are expensed as incurred. The agreements may also require that the Company provide funding to its partners for research programs. These costs are expensed as incurred.

**Other** The Company accrues estimated costs for clinical and preclinical studies performed by contract research organizations or by internal staff based on the total of the costs incurred through the balance sheet date. The Company monitors the progress of the trials and their related activities to the extent possible, and adjusts the accruals accordingly.

### **Selling, General and Administrative Expenses**

**Co-promotion Expenses** Co-promotion expense in connection with the Company's agreement with AI to co-promote Synagis in the U.S. is recognized as general and administrative expense concurrently with the recognition of product revenue, net of allowances for estimated chargebacks, returns, discounts, and government rebates, and is calculated based on a contractually stipulated co-promotion percentage. Any adjustments to co-promotion expense that result from variances between estimated and actual net sales are recorded as an adjustment to expense in the quarter they become known.

**Bad debt expense** The Company estimates the level of bad debts as a percentage of gross trade accounts receivable balances outstanding at the end of the period, based upon our assessment of the concentration of credit risk, the financial condition and environment of our customers, and the level of credit insurance obtained on customer balances. Because of the seasonal nature of our largest product, Synagis, our accounts receivable balances fluctuate significantly. Accordingly, the allowance for doubtful accounts also fluctuates. For all periods presented, bad debt expense has been reclassified as selling, general and administrative expense in the Consolidated Statements of Operations.

53

**Advertising Expense** The Company expenses production costs of advertising as incurred. Advertising costs for television time and space in publications are deferred until the first advertisement occurs. Advertising expense for the years ended December 31, 2003, 2002 and 2001 was \$8.1 million, \$7.4 million, and \$7.0 million, respectively.

**Property and Equipment** Property and equipment are stated at cost. Interest cost incurred during the period of construction of plant and equipment is capitalized until the asset is placed in service, after FDA licensure of the facility is obtained. Depreciation and amortization expense commence when the asset is placed in service for its intended purpose. Depreciation and amortization is computed using the straight-line method based upon the following estimated useful lives:

	<u>Years</u>
Building and improvements	15-30
Manufacturing, laboratory, and facility equipment	5-15
Office furniture, computers and equipment	3-7

Amortization of leasehold improvements is computed on the straight-line method based on the shorter of the estimated useful life of the improvement or the term of the lease. Depreciation and amortization expense for the years ended December 31, 2003, 2002, and 2001 was \$24.0 million, \$20.7 million, and \$9.1 million, respectively. Upon the disposition of assets, the costs and related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the statements of operations. Repairs and maintenance costs are expensed as incurred and were \$6.8 million, \$7.0 million, and \$3.3 million for the years ended December 31, 2003, 2002, and 2001, respectively.

The Company evaluates the recoverability of the carrying value of property and equipment. The Company considers historical performance and anticipated future results in its evaluation of the potential impairment. Accordingly, when the indicators of impairment are present, the Company evaluates the carrying value of these assets in relation to the operating performance of the business and future undiscounted cash flows expected to result from the use of these assets. Impairment losses are recognized when the sum of the expected future cash flows are less than the assets' carrying value.

**Intangible Assets** Intangible assets are stated at amortized cost. The Company reviews its intangible assets for impairment annually or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Intangible assets at December 31 are comprised of the following (in millions):

	<u>2003</u>	<u>2002</u>
Worldwide collaborative agreement with Wyeth	\$ 90.0	\$ 90.0
Contract manufacturing agreement with Evans	39.0	39.0
Other intangible assets	0.4	0.4
	<u>129.4</u>	<u>129.4</u>
Less accumulated amortization	(32.7)	(16.1)
	<u>\$ 96.7</u>	<u>\$ 113.3</u>

Amortization of intangible assets is computed on the straight-line method based on the estimated useful lives of the assets. Amortization expense for the years ended December 31, 2003 and 2002 was \$13.7 million and \$16.1 million, respectively. No amortization expense was incurred in 2001. The estimated aggregate amortization for each of the next five years is as follows: 2004, \$16.4 million; 2005, \$16.4 million; 2006, \$12.0 million; 2007, \$7.7 million; and 2008, \$7.7 million.

54

**Goodwill** Goodwill represents the excess of the Company's cost to acquire MedImmune Vaccines over the net of the amounts assigned to assets acquired and liabilities assumed. Goodwill is not amortized, but is evaluated for impairment annually or whenever events or changes in circumstances suggest that the carrying amount may not be recoverable. During 2003, the Company reduced goodwill recorded in the acquisition by \$2.4 million, reflecting additional deferred tax assets for adjustments relating to pre-acquisition items.

**Derivative Instruments** The Company is obligated to make certain payments to foreign suppliers in local currency. To hedge the effect of fluctuating foreign currencies in its financial statements, the Company may enter into foreign forward exchange contracts. Gains or losses associated with the forward contracts are computed as the difference between the foreign currency contract amount at the spot rate on the balance sheet date and the forward rate on the contract date.

All derivative instruments are recorded on the balance sheet at fair value. Changes in fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether a derivative is designated as part of a hedge transaction and if so, depending on the type of hedge transaction. For foreign currency cash-flow hedge transactions in which the Company is hedging the variability of cash flows related to inventory purchases, changes in the fair value of the derivative instruments are reported in other comprehensive income. The gains and losses on these derivatives that are reported in other comprehensive income are reclassified as earnings or losses in the periods in which the related inventory is sold. The ineffective portion, if any, of all hedges or gains or losses on cash-flow hedges related to inventory transactions that subsequently become not probable of occurring are recognized in the current period. In accordance with the transition provisions of SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities", the Company recorded a net-of-tax cumulative-effect-type gain of \$0.3 million in accumulated other comprehensive income as of January 1, 2001 to recognize at fair value all derivatives, which are designated as foreign currency cash-flow hedging instruments.

As of December 31, 2002, the Company had outstanding forward Euro contracts for the purchase of 1.1 million Euros, all expiring within one year, with a fair value of \$0.3 million. As of December 31, 2003 and December 31, 2001, the Company had no outstanding forward contracts. During the year ended December 31, 2002, net unrealized gains on forward exchange contracts, net of tax, of \$0.6 million, were reclassified as earnings during the year as the related inventory was sold. During the year ended December 31, 2002, the Company reclassified a gain of \$0.2 million to current period earnings for hedge ineffectiveness related to forward exchange contracts, respectively.

The Company intends to liquidate its holdings in certain equity securities in its portfolio, over a period of approximately one year. To hedge the risk of market fluctuations, the Company has entered into equity derivative contracts which have been designated as cash flow hedges. As of December 31, 2003, the unrealized gain on the marketable equity securities related to this hedge was \$13.2 million while the fair value of the derivative contracts was a liability of \$3.5 million, resulting in a net unrealized gain on the hedging transaction.

**Income Taxes** Deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized and are reversed at such time that realization is believed to be more likely than not. Future reversals of valuation allowance on MedImmune Vaccine's acquired deferred tax assets will first be applied against goodwill and other intangibles before recognition of a benefit in the consolidated statement of operations. Income tax expense is the tax payable for the period and the change during the period in deferred tax assets and

liabilities, exclusive of amounts related to the exercise of stock options which benefit is recognized directly as an increase in shareholders' equity.

**Earnings Per Share** Basic earnings per share is computed based on the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed based on the weighted average shares outstanding adjusted for all dilutive potential common shares. The dilutive impact, if any, of common stock equivalents outstanding during the period, including outstanding stock options and warrants, is measured by the treasury stock method. The dilutive impact, if any, of the Company's 5<sup>1</sup>/<sub>4</sub>% Notes is measured using the if-converted method. The 1% Notes are considered contingent convertible securities, meaning they are eligible for conversion to common stock only if certain requirements are met, and were excluded from the diluted earnings per share calculations for all periods presented. Potential common shares are not included in the computation of diluted earnings per share if they are antidilutive.

**Comprehensive Income** Comprehensive income is comprised of net earnings and other comprehensive income, which includes certain changes in equity that are excluded from net earnings. Other comprehensive income includes certain changes in equity that are excluded from net earnings or loss, such as translation adjustments, unrealized holding gains and losses on available-for-sale marketable securities, and unrealized gains and losses on hedging instruments.



## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

**Stock-based Compensation** Compensation costs attributable to stock option and similar plans are recognized based on any excess of the quoted market price of the stock on the date of grant over the amount the employee is required to pay to acquire the stock, in accordance with the intrinsic-value method under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"). Such amount, if any, is accrued over the related vesting period, as appropriate.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure" ("SFAS 148"). SFAS 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The alternative methods of transition and additional disclosure requirements of SFAS 148 were effective January 1, 2003.

56

The following table illustrates the effect on net earnings and earnings per share if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation (in millions, except per share data):

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Net earnings (loss), as reported	\$ 183.2	\$ (1,098.0)	\$ 149.0
Add: stock-based employee compensation expense included in historical results for the vesting of stock options assumed in conjunction with the Acquisition, calculated in accordance with FIN 44, "Accounting for Certain Transactions Involving Stock Compensation-an Interpretation of APB 25, net of related tax effect	2.5	12.1	
Deduct: stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effect	(87.5)	(96.3)	(82.0)
Pro forma net earnings (loss)	\$ 98.2	\$ (1,182.2)	\$ 67.0
Basic earnings (loss) per share, as reported	\$ 0.73	\$ (4.40)	\$ 0.70
Basic earnings (loss) per share, pro forma	\$ 0.39	\$ (4.74)	\$ 0.31
Diluted earnings (loss) per share, as reported	\$ 0.72	\$ (4.40)	\$ 0.68
Diluted earnings (loss) per share, pro forma	\$ 0.39	\$ (4.74)	\$ 0.31

The pro forma expense related to the stock options is recognized over the vesting period, generally five years. The fair value of each option grant was estimated using the Black-Scholes option pricing model with the following weighted average assumptions for each year:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Risk-free interest rate	3.27%	4.16%	4.72%
Expected life of options years	5	6	6
Expected stock price volatility	51%	53%	69%
Expected dividend yield	N/A	N/A	N/A

To better estimate the future expected stock price volatility, during 2002 the Company changed its method of calculating historical volatility from using daily stock price observations to using monthly observations over the expected life of the options.

The weighted average fair value of options granted during 2003, 2002, and 2001 was \$16.55, \$20.56, and \$25.23, respectively.

**Defined Contribution Plans** The Company sponsors a defined contribution plan under Section 401(k) of the Internal Revenue Code covering substantially all full-time U.S. employees. Employee contributions are voluntary and are determined on an individual basis subject to the maximum allowable under federal tax regulations. Participants are always fully vested in their contributions. The Company also makes employer contributions, which primarily vest pro ratably over three years of service. During 2003, 2002, and 2001, the Company contributed approximately \$2.4 million, \$1.9 million, and \$1.1 million, respectively, in cash to the plan. The Company also sponsors various defined contribution savings plans covering its full-time non-U.S. employees.

**Reclassification** Certain prior year amounts have been reclassified to conform to the current presentation.

**Use of Estimates** The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities at the financial statement date and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**New Accounting Standards** In 2003, the FASB issued FIN No. 46, "Consolidation of Variable Interest Entities, an interpretation of Accounting Research Bulletin No. 51." FIN No. 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. In accordance with the adoption provisions of FIN No. 46, during 2003 the Company adopted the provisions as they relate to the Company's contractual relationships with variable interest entities established subsequent to January 31, 2003, with an immaterial impact to the Company's consolidated financial position, results of operations and cash flows. The effective date for applying the provisions of FIN No. 46 for interests held by public entities in variable interest entities created before February 1, 2003 has been deferred to periods ending after March 14, 2004. The Company believes the impact of applying the consolidation provisions of FIN No. 46 relative to its investments in variable interest entities established prior to February 1, 2003 will be immaterial to its consolidated financial position, results of operations and cash flows.

### 3. ACQUISITION

On January 10, 2002, the Company completed the Acquisition through an exchange offer and merger transaction. Through the Acquisition, the Company obtained a new product, FluMist, which is a nasally delivered, live, attenuated virus vaccine. The Acquisition was accounted for as a purchase and, accordingly, the results of MedImmune Vaccines' operations have been included with the Company's operations since January 10, 2002.

Under the terms of the Acquisition, the Company exchanged approximately 34.0 million of its common shares for 100% of the outstanding common stock of Aviron. Additionally, the Company assumed outstanding options and warrants for which approximately 7.0 million shares of the Company's common stock are issuable. Originally, the holders of Aviron's Notes could have converted the 5<sup>1</sup>/<sub>4</sub>% Notes into a total of approximately 3.4 million shares of the Company's common stock, based on a conversion price of \$58.14 per share. During 2003, the Company retired approximately \$32.4 million of the 5<sup>1</sup>/<sub>4</sub>% Notes. As of December 31, 2003 the 5<sup>1</sup>/<sub>4</sub>% Notes may be converted into approximately 2.9 million shares of the Company's common stock, based on a conversion price of \$58.14. The Company has notified the holders of the 5<sup>1</sup>/<sub>4</sub>% Notes of its intention to redeem as of March 31, 2004.

The Company's aggregate purchase consideration was approximately \$1.6 billion, as follows (in millions):

Common stock	\$ 1,497.3
Assumption of Aviron's options and warrants, less intrinsic value of unvested portion	128.0
Transaction costs	9.8
	<hr/>
	\$ 1,635.1
	<hr/>

The value of common shares issued was \$44.10 per share, based on the closing market price of the Company's common stock on November 30, 2001, the last business day prior to the signing of the merger agreement. The fair value of options and warrants assumed in the transaction was estimated using the Black-Scholes option pricing model.

The following table summarizes the final estimated fair values (in millions) of the assets acquired and liabilities assumed in accordance with the acquisition.

Assets:	
Cash and marketable securities	\$ 417.5
Other current assets	24.9
Other assets	45.8
Deferred tax assets	130.0

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

Intangible assets	129.4
In-process research and development	1,179.3
Goodwill	13.6
Total assets	\$ 1,940.5
Liabilities:	
Current liabilities	\$ 49.2
Restructuring liability	15.8
Long-term debt	211.4
Long-term obligations	28.5
Other liabilities	0.5
Total liabilities	305.4
Net assets acquired	\$ 1,635.1

**Intangible Assets** Of the \$129.4 million of acquired intangible assets, \$90.0 million was assigned to MedImmune Vaccines' worldwide collaborative agreement with Wyeth for the development, manufacture, distribution, marketing, promotion, and sale of FluMist, which is subject to amortization over its estimated useful life of approximately 11 years. The Company estimated the fair value of the Wyeth agreement using the sum of the probability-adjusted scenarios under the income approach. In applying this method, the Company relied on revenue assumptions, profitability assumptions and anticipated approval dates. The remaining \$39.0 million was assigned to MedImmune Vaccines' contract manufacturing agreement with Evans Vaccines Limited, which is subject to amortization over its estimated useful life of approximately four years. The Company estimated the fair value of the Evans agreement using the cost approach, which is based on the theory that a prudent investor would pay no more for an asset than the amount for which the asset could be replaced. In its analysis, the Company reduced replacement cost for such factors as physical deterioration and functional or economic obsolescence.

**In-Process Research and Development** Approximately \$1,179.3 million of the purchase price was allocated to acquired research and development assets that were written off at the date of acquisition as a separate component of the Company's results of operations. The amount represents the fair value of purchased in-process technology for projects, principally FluMist, which, as of the date of the acquisition, had not yet reached technological feasibility and had no alternative future use.

**Goodwill** Approximately \$16.0 million in goodwill was recognized in the allocation of the purchase price, none of which is expected to be deductible for tax purposes. In December 2003, the Company further reduced goodwill and increased deferred tax assets by \$2.4 million to reflect an adjustment relating to pre-acquisition items. In 2002, the Company recorded net purchase price adjustments of \$1.3 million; net reversals to the restructuring liability of \$0.2 million (discussed below); a net increase of \$3.7 million and a net reduction of \$0.9 million to the fair values assigned to certain depreciable assets and certain liabilities, respectively, based on a final assessment of their net realizable value; and a net decrease in the fair value assigned to net deferred tax assets of \$6.4 million resulting from the revisions to the purchase price allocation; which in the aggregate resulted in an increase to goodwill of

59

\$0.3 million. The Company performed its annual impairment analysis during the fourth quarter of 2003, and determined that the goodwill was not impaired.

**Restructuring Liability** Included in the final allocation of acquisition cost was a restructuring liability of \$15.8 million for estimated costs associated with the Company's restructuring plan. The restructuring plan was originally formulated and announced to employees in December 2001, to consolidate and restructure certain functions, including the involuntary termination of eight executives and 52 other employees of MedImmune Vaccines from various functions and levels.

During 2003, the Company incurred \$0.7 million of restructuring charges, resulting in a \$0.3 million reserve balance at December 31, 2003. At December 31, 2002, the remaining restructuring reserve, which consisted of other facility-related costs, was \$1.0 million.

**Transaction Costs** Included in the final allocation of acquisition costs were transaction costs of \$9.8 million, which primarily consist of investment banking, accounting and legal fees incurred by the Company.

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

**Pro Forma Data** The following unaudited pro forma condensed combined supplemental data present the revenues, net earnings and earnings per share of the combined entity as though the business combination had been completed as of January 1, 2002 and 2001, respectively. This data gives effect to actual operating results prior to the acquisition, adjusted to include the pro forma effect of amortization of intangibles, deferred stock compensation costs, the elimination of the non-recurring charge for acquired in-process research and development, the tax effects to the pro forma adjustments and the recognition of the tax benefits arising from Aviron's net loss for the 2001 period. This data is not necessarily an indication of the results that would have been achieved had the transaction been consummated as of the dates indicated or that may be achieved in the future (in millions, except per share data).

	Year Ended December 31,	
	2002	2001
Revenues	\$ 852.7	\$ 637.7
Net earnings	\$ 81.3(1)	\$ 56.5
Diluted earnings per share	\$ 0.32(1)	\$ 0.22

(1) Excludes a non-recurring charge of \$1,179.3 million for acquired in-process research and development.

#### 4. SEGMENT, GEOGRAPHIC AND PRODUCT INFORMATION

The Company's operations are considered one operating segment as the Company's chief operating decision makers review the profit and loss of the Company on an aggregate basis and manage the operations of the Company as a single operating segment.

The Company sells its products primarily to a limited number of pharmaceutical wholesalers and distributors. Effective for the 2003/2004 RSV season, the Company reduced the number of U.S. specialty distributors in its Synagis network from over 100 in the 2002/2003 season to about a dozen specialty distributors. In addition, the Company reduced the number of Synagis wholesalers and home health care agencies it will use. The changes were made to achieve a higher level of service to patients through contractual requirements for the members of the Synagis network to provide the downstream service related to Synagis. The Company believes the selection criteria used in this process should also mitigate any risks associated with a higher concentration of credit among fewer creditors. Customers

60

individually accounting for at least ten percent of the Company's product sales during the past three years are as follows:

	2003	2002	2001
Amerisource Bergen Corp.	29%	27%	26%
Cardinal Health, Inc.	18%	17%	18%
McKesson HBOC, Inc.	12%	13%	13%
Caremark Rx, Inc.	10%	11%	12%
	69%	68%	69%
Total % of product sales	69%	68%	69%

The Company has contractual agreements with AI, for distribution of Synagis outside of the United States and with affiliates of Schering for international distribution of Ethyol. The Company also relies on a limited number of distributor agents/affiliates to sell CytoGam and NeuTrexin internationally. The breakdown of product sales by geographic region is as follows (in millions):

	2003	2002	2001
United States	\$ 911.3	\$ 752.9	\$ 533.5
All other	81.3	38.0	48.0

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Total product sales	992.6	790.9	581.5
Other revenue, primarily U.S.	61.7	61.8	39.2
<b>Total revenues</b>	<b>\$ 1,054.3</b>	<b>\$ 852.7</b>	<b>\$ 620.7</b>

The breakdown of long-lived assets by geographic region is as follows (in millions):

	<u>2003</u>	<u>2002</u>	<u>2001</u>
United States	\$ 222.5	\$ 161.0	\$ 92.5
All other	51.1	23.0	2.9
<b>Total long-lived assets</b>	<b>\$ 273.6</b>	<b>\$ 184.0</b>	<b>\$ 95.4</b>

Other revenue of \$61.7 million, \$61.8 million, and \$39.2 million in 2003, 2002, and 2001, respectively, consists mainly of United States distribution, licensing, milestone revenues, corporate funding, and contract manufacturing revenues.

61

## 5. MARKETABLE SECURITIES

Investments in marketable securities are comprised of the following (in millions):

	<u>Principal Amount</u>	<u>Cost/ Amortized Cost</u>	<u>Fair Value at Balance Sheet Date</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>
<i>December 31, 2003:</i>					
Equity Securities	\$ 2.5	\$ 2.5	\$ 15.7	\$ 13.2	\$
U.S. Government and Agencies	102.9	106.9	109.1	2.2	
Corporate Debt Securities	1,134.2	1,187.3	1,214.5	30.8	(3.6)
Foreign Bank Debt Securities	41.3	43.0	45.3	2.3	
<b>Total</b>	<b>\$ 1,280.9</b>	<b>\$ 1,339.7</b>	<b>\$ 1,384.6</b>	<b>\$ 48.5</b>	<b>\$ (3.6)</b>
<i>December 31, 2002:</i>					
Equity Securities	\$	\$ 1.9	\$ 1.9	\$	\$
U.S. Government and Agencies	245.9	251.0	254.2	3.2	
Corporate Debt Securities	900.4	935.4	967.9	32.9	(0.3)
Foreign Bank Debt Securities	64.6	66.3	69.0	2.6	
<b>Total</b>	<b>\$ 1,210.9</b>	<b>\$ 1,254.6</b>	<b>\$ 1,293.0</b>	<b>\$ 38.7</b>	<b>\$ (0.3)</b>

The amortized cost and fair market value of investments at December 31, 2003 and 2002, by contractual maturities are (in millions):

<u>2003</u>		<u>2002</u>	
<u>Cost/ Amortized Cost</u>	<u>Fair Value</u>	<u>Cost/ Amortized Cost</u>	<u>Fair Value</u>

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

	2003		2002	
Equity Securities	\$ 2.5	\$ 15.7	\$ 1.9	\$ 1.9
Due in one year or less	253.7	257.0	393.4	395.0
Due after one year through two years	164.6	171.7	252.6	259.6
Due after two years through five years	761.2	780.2	496.3	521.9
Due after five years through seven years	157.7	160.0	110.4	114.6
Total	\$ 1,339.7	\$ 1,384.6	\$ 1,254.6	\$ 1,293.0

Gross gains recognized on sales of securities in 2003, 2002 and 2001 were \$5.9 million, \$0.9 million and \$2.1 million, respectively, as determined by specific identification. Gross losses recognized on sales of securities were immaterial during 2003, 2002 and 2001, as determined by specific identification.

During 2002, the Company determined that the declines in fair value below the cost basis of certain investments were other than temporary, based primarily on the duration and magnitude of the declines in fair value as well as the financial condition and near-term prospects of the investee companies. For the year ended December 31, 2002, the Company recorded realized losses of \$4.5 million to write-down the cost basis of the investments to fair value. The Company recorded no such losses in 2003.

62

## 6. INVENTORY

Inventory, net of valuation reserves, at December 31, is comprised of the following (in millions):

	2003	2002
Raw materials	\$ 11.6	\$ 30.4
Work in process	39.3	19.4
Finished goods	40.8	10.2
	\$ 91.7	\$ 60.0

During 2003, the Company recorded \$37.5 million of valuation reserves in cost of goods sold to reflect total FluMist inventories at net realizable value.

## 7. PROPERTY AND EQUIPMENT

Property and equipment, stated at cost at December 31, is comprised of the following (in millions):

	2003	2002
Land and land improvements	\$ 27.9	\$ 15.7
Buildings and building improvements	55.2	52.6
Leasehold improvements	36.2	33.9
Laboratory, manufacturing and facilities equipment	57.0	50.1
Office furniture, computers, and equipment	40.4	28.5
Construction in progress	135.6	56.7
	352.3	237.5
Less accumulated depreciation and amortization	(78.7)	(53.5)
	\$ 273.6	\$ 184.0

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

2003	2002

As of December 31, 2003, construction in progress includes \$62.7 million of engineering and construction costs and other professional fees related to the first phase of the headquarters and research and development facility, which will feature a complex totaling approximately 220,000 square feet. In addition, construction in progress includes \$70.0 million of engineering, construction and equipment costs related to the Company's manufacturing facilities in Pennsylvania and Speke, the United Kingdom. As of December 31, 2002, construction in progress primarily included costs associated with the headquarters and research and development facility, and the projects in Pennsylvania and the United Kingdom. Additionally, there were costs associated with the expansion of the cell culture production area in the FMC, which was placed in service during 2002. The Company expects to take occupancy of the new headquarters and research and development facility in the first quarter of 2004. The second phase of construction, which is for the Pilot Plant Facility, commenced in September 2003 at a total estimated cost of \$82 million. The Company expects the second phase of the project to be complete in the fourth quarter of 2005.

In connection with the Acquisition, the Company acquired property, plant and equipment valued at approximately \$42.5 million, comprised primarily of leasehold improvements, lab, manufacturing and office equipment, and partially-constructed manufacturing facilities.

Effective November 2002, the Company outsourced the process of converting human plasma to the critical intermediate used in CytoGam production to a third party manufacturer. Prior to that date, the process was performed at the Company's Frederick Manufacturing Facility. Accordingly, the Company recorded a \$12.9 million impairment charge, recorded in other operating expenses, during the fourth quarter of 2002 for the write-off of certain plasma manufacturing assets.

63

Interest costs capitalized in connection with the Company's construction activities totaled \$2.9 million and \$0.9 million in 2003 and 2002, respectively. Interest costs capitalized during 2001 were not material.

### 8. ACCRUED EXPENSES

Accrued expenses at December 31, are comprised of the following (in millions):

	2003	2002
Co-promotion expenses	\$ 73.0	\$ 60.1
Rebates due to government purchasers	42.4	26.2
Research and development expense	27.5	16.1
Sales and marketing costs	19.2	17.2
Construction costs	13.1	3.5
Bonuses	9.8	11.0
Other	33.0	23.3
	\$ 218.0	\$ 157.4

### 9. FACILITIES LEASES

The Company leases warehouse, laboratory and administrative space under numerous operating leases. Under the leases, the Company is obligated to pay a basic monthly rent, which will increase each lease year. The leases also require the Company to pay for utilities and its proportionate share of taxes, assessments, insurance and maintenance costs. Rent expense for the years ended December 31, 2003, 2002, and 2001 was \$9.3 million, \$9.0 million, and \$2.2 million, respectively.

The Company's future minimum lease payments under operating leases are as follows (in millions):

Year Ending December 31,	
2004	\$ 8.8
2005	6.5

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

Year Ending December 31,

2006	4.5
2007	2.8
2008	2.5
Thereafter	29.2
	\$ 54.3

The Company expects to take occupancy of the first phase of our headquarters and research and development facility, a complex of approximately 220,000 square feet, in March 2004. The majority of the existing space in Gaithersburg is leased through 2006, a portion of which will be offered for sublease. There can be no guarantee that the Company will be successful in subleasing the space.

64

**10. LONG-TERM DEBT**

Long-term debt at December 31, is comprised of the following (in millions):

	2003	2002
1% Convertible Senior Notes, due 2023	\$ 500.0	\$
5 <sup>1</sup> / <sub>4</sub> % Convertible Subordinated Notes, due 2008	174.1	209.6
4% notes due to Maryland Department of Business and Economic Development, due 2016	5.1	5.4
7.53% note due to Maryland Industrial Development Finance Authority, due 2007 (collectively with the 4% notes referred to as the "Maryland Notes")	2.6	3.1
Note due to Cooperative Rabobank, B.A., due 2009, variable interest rate	0.3	0.3
	682.1	218.4
Less current portion included in other current liabilities	(0.9)	(0.8)
	\$ 681.2	\$ 217.6

Maturities of the Company's long-term debt, which do not include the premium on the 5<sup>1</sup>/<sub>4</sub> notes, for the next five years are as follows: 2004, \$0.9 million; 2005, \$1.0 million; 2006, \$1.0 million; 2007, \$1.3 million; and 2008, \$168.1 million.

**1% Convertible Senior Notes** During July 2003, the Company issued \$500 million aggregate principal amount of convertible senior notes due 2023 in a private placement. These notes bear interest at 1% per annum payable semi-annually in arrears on January 15 and July 15 of each year. Beginning July 2006, the Company will pay contingent interest on these notes during a six-month interest period if the average trading price of these notes is above a specified level. Under certain circumstances, these notes will be convertible into the Company's common stock at an initial conversion price of approximately \$68.18 per share. On or after July 15, 2006, the Company may at its option redeem all or a portion of these notes for cash at a redemption price equal to 100% of the principal amount of the 1% Notes to be redeemed, plus any accrued and unpaid interest; contingent interest, if any; and liquidated damages, if any. In addition, on each of July 15, 2006, July 15, 2009, July 15, 2013, and July 15, 2019, holders may require the Company to purchase all or a portion of their 1% Notes for cash at 100% of the principal amount of the 1% Notes to be purchased, plus any accrued and unpaid interest; contingent interest, if any; and liquidated damages, if any. The estimated fair value of the 1% Notes as of December 31, 2003 was \$475.0 million, based on quoted market prices.

**Convertible Subordinated Notes** Following the Acquisition, MedImmune Vaccines remained obligated for its outstanding indebtedness, which included \$200.0 million aggregate principal amount of the 5<sup>1</sup>/<sub>4</sub>% Notes. Approximately \$211.4 million of the acquisition cost was allocated to the 5<sup>1</sup>/<sub>4</sub>% Notes, which represented the fair value as of the acquisition date, based on quoted market prices. During 2003, the Company retired approximately \$32.4 million principal amount of the 5<sup>1</sup>/<sub>4</sub>% Notes for approximately \$33.1 million. The retirement resulted in a net ordinary gain of \$0.5 million reflecting the accelerated amortization of premium. The outstanding 5<sup>1</sup>/<sub>4</sub>% Notes are convertible into an



## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

aggregate of 2.9 million shares of the Company's common stock, based on a conversion price of \$58.14, at any time on or before February 1, 2008. The Company may redeem the 5<sup>1</sup>/<sub>4</sub>% Notes beginning in February 2004, at redemption prices declining from 103% of their principal amount in 2004 to 100% in 2008, plus accrued interest. Interest is payable semi-annually in arrears in cash on February 1 and August 1 each year. The Company elected on February 25, 2004 to redeem the entire remaining amount of the issue at approximately 103% of its principal amount in the first quarter of 2004. The estimated fair value of the 5<sup>1</sup>/<sub>4</sub>% Notes as of December 31, 2003 and December 31, 2002 was \$173.4 million and \$198.2 million, respectively, based on quoted market prices.

65

**Collateralized Loans** The Maryland Notes are collateralized by the land, buildings and building fixtures of the FMC. The agreements include a provision for early retirement of the notes by the Company. Pursuant to the terms of the agreements, the Company is required to meet certain financial and non-financial covenants including maintaining minimum cash balances and net worth ratios. The Company maintains a \$0.4 million compensating balance related to the Maryland Notes, which is included in other assets.

The mortgage loan with Cooperative Rabobank B.A. is held by Company's subsidiary, USB Pharma B.V., and is collateralized by the land and buildings of its manufacturing facility in Nijmegen, the Netherlands and guaranteed by the Company. Proceeds from the loan were used to partially fund the purchase of additional equipment for the facility. The mortgage loan, for which principal payments began in March 1995, has a 15-year term and bears interest at a quarterly variable rate. The interest rate as of December 31, 2003 and December 31, 2002 was 5.05% and 5.85%, respectively. The estimated fair values of the Company's collateralized loans at December 31, 2003 and 2002, respectively, based on quoted market prices or discounted cash flows using currently available borrowing rates, were \$8.4 million and \$9.3 million compared to the carrying values of \$8.0 million and \$8.8 million.

### 11. SHAREHOLDERS' EQUITY

Pursuant to the terms of the Stockholder Rights Plan adopted by the Company's Board of Directors, common stock purchase rights ("Rights") were distributed as a dividend at the rate of one Right for each share of common stock of the Company held by stockholders of record as of the close of business on July 21, 1997. The Rights will be exercisable only if a person or group acquires beneficial ownership of 20 percent or more of the Company's common stock or commences a tender or exchange offer upon consummation of which such a person or group would beneficially own 20% or more of the Company's stock. The Rights will expire on July 9, 2007.

In May 2003, the Company's shareholders approved an amendment to the Company's Restated Certificate of Incorporation to increase the authorized number of shares of common stock from 320 million to 420 million.

In July 2003, our Board of Directors authorized the repurchase, over a two-year period, of up to \$500 million of the Company's common stock on the open market or in privately negotiated transactions, pursuant to terms management deems appropriate and at such times it may designate. Under the stock repurchase program, we repurchased 6.2 million shares of our common stock at a total cost of \$229.8 million, or an average cost of \$36.83 per share through December 31, 2003. The Company also entered into a 10b5-1 trading plan to repurchase shares in the open market during those periods each quarter when trading in our common stock is restricted under our insider trading policy. Of the shares repurchased, approximately 0.7 million shares were purchased under the 10b5-1 trading plan. As of February 29, 2004, we had not purchased any additional shares since October 7, 2003. The Company will hold repurchased shares as treasury shares and intends to use them for general corporate purposes, including but not limited to acquisition-related transactions and for issuance upon exercise of outstanding stock options.

66

### 12. EARNINGS PER SHARE

The following is a reconciliation of the denominators of the diluted EPS computation for the years ended December 31, 2003, 2002, and 2001. There are no reconciling items to the numerator for the EPS computation for the periods reported.

	2003	2002	2001
Denominator (in millions):			
Weighted average shares outstanding	250.1	249.6	213.4
Effect of dilutive securities:			
Stock options and warrants	3.7		6.7

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

	2003	2002	2001
	_____	_____	_____
	_____	_____	_____
Denominator for diluted EPS	253.8	249.6	220.1
	_____	_____	_____

The Company incurred a net loss for the year ended December 31, 2002 and, accordingly, did not assume exercise or conversion of potential common shares for the year, as follows, because to do so would have been antidilutive:

	(in millions)
	_____
Stock options, at prices ranging from \$0.47 to \$83.25	28.6
Warrants, at \$9.30 per share	0.4
Notes, at a conversion price of \$58.14	3.4
	_____
Total potential common shares	32.4
	_____

If option exercise prices are greater than the average market price of the Company's common stock for the period presented, the effect of including such options in the earnings per share calculation is anti-dilutive. As a result, options to purchase 14.8 million shares of the Company's common stock with exercise prices ranging from \$32.38 to \$83.25 per share were outstanding during 2003, but were excluded from the computation of diluted earnings per share. Additionally, options to purchase 6.6 million shares of the Company's common stock with exercise prices ranging from \$40.50 to \$83.25 were outstanding during 2001, but were excluded from the computation of diluted earnings per share. The 1% Notes are considered contingent convertible securities, meaning they are eligible for conversion to common stock only if certain requirements are met, and were excluded from the diluted earnings per share calculations for all periods presented. The 1% Notes represent 7.3 million potential shares of common stock issuable upon conversion.

### 13. COMMON STOCK EQUIVALENTS

The Company currently grants stock options under certain of the following stock option plans. At the Company's annual meeting in May 2003, the Company's shareholders approved the establishment of the 2003 Non-Employee Directors Stock Option Plan, and reserved 800,000 shares of common stock for issuance thereunder. In addition, the Company's shareholders voted to increase the maximum

67

number of shares of common stock reserved for issuance under the 1999 Plan from 25,250,000 to 31,250,000 shares.

Plan	Description	Shares Authorized (in millions)
_____	_____	_____
Old Plan	Provides option incentives to employees, consultants and advisors of the Company	1.5
1991 Plan	Provides option incentives to employees, consultants and advisors of the Company	33.0
1993 Non-Employee Directors Plan	Provides option incentives to non-employee directors	1.5
1999 Plan	Provides option incentives to employees, consultants and advisors of the Company	31.3
2003 Non-Employee Directors Plan	Provides option incentives to non-employee directors	0.8

The following compensation plans, for which no future grants will be made, were acquired by the Company in 1999 in connection with its acquisition of MedImmune Oncology.

Plan	Description	Shares Authorized (in millions)
_____	_____	_____

Non-Executive Stock Option Plan	Provided option incentives to employees who are not officers or directors of MedImmune Oncology, consultants and advisors of the Company	1.0
1996 Non-Employee Directors Stock Option Plan	Provided option incentives to elected non-employee directors of MedImmune Oncology	

In addition, the following compensation plans, for which no future grants will be made, were acquired by the Company in 2002 in connection with its acquisition of MedImmune Vaccines.

Plan	Description	Shares Authorized (in millions)
1996 Equity Incentive Plan ("1996 Plan")	Provides for the grant of incentive and nonstatutory stock options to employees and consultants of MedImmune Vaccines	4.7
1999 Non-Officer Equity Incentive Plan ("1999 Plan")	Provides for the grant of nonstatutory stock options, stock bonuses, rights to purchase restricted stock, and stock appreciation rights to consultants and employees who are not officers or directors of MedImmune Vaccines	4.2

Options under all plans normally vest over a three to five year period and have a maximum term of 10 years. The Company has reserved a total of 11.5 million shares of common stock for issuance under these plans as of December 31, 2003.

Related stock option activity, is as follows (shares in millions):

	1991 and 1999 Plans		Non-employee Directors Plans		MedImmune Oncology Plans		MedImmune Vaccines Plans	
	Shares	Price per share(1)	Shares	Price per share(1)	Shares	Price per share(1)	Shares	Price per share(1)
Balance Dec. 31, 2000	20.4	\$ 28.15	0.6	\$ 24.23	0.2	\$ 25.52		\$
Granted	4.7	38.14	0.2	47.20				
Exercised	(3.0)	7.15	(0.1)	12.51	(0.2)	20.70		
Canceled	(1.9)	43.87						
Balance Dec. 31, 2001	20.2	32.17	0.7	29.22	0.0			
Acquisition							6.5	27.25
Granted	5.9	36.74	0.2	28.90				
Exercised	(0.8)	6.75					(1.8)	20.28
Canceled	(1.2)	44.97					(1.1)	36.06
Balance Dec. 31, 2002	24.1	33.45	0.9	29.53	0.0		3.6	\$ 28.17
Granted	5.4	30.18	0.2	35.87				
Exercised	(2.0)	11.61	(0.1)	2.02			(0.5)	21.30
Canceled	(1.4)	41.33					(0.5)	33.86
Balance Dec 31, 2003	26.1	\$ 34.00	1.0	\$ 30.52	0.0	\$	2.6	\$ 29.82

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

(1)

Price per share is the weighted average exercise price.

Additional information related to the plans as of December 31, 2003 is as follows (shares in millions):

Range of exercise prices	Options Outstanding			Options Exercisable	
	Options outstanding	Wtd Avg remaining contractual life (yrs)	Wtd Avg Ex. Price	Options Exercisable	Wtd Avg Ex. Price
\$ 0.01-\$10.00	3.0	3.1	\$ 5.06	3.0	\$ 5.06
\$ 10.01-\$20.00	3.4	5.3	\$ 17.16	3.1	\$ 17.02
\$ 20.01-\$30.00	7.9	7.9	\$ 27.47	3.1	\$ 26.22
\$ 30.01-\$40.00	6.1	7.0	\$ 36.51	3.4	\$ 37.23
\$ 40.01-\$50.00	4.6	7.5	\$ 42.38	2.3	\$ 42.67
\$ 50.01-\$60.00	0.6	6.4	\$ 56.54	0.4	\$ 56.57
\$ 60.01-\$70.00	3.7	6.0	\$ 60.94	2.7	\$ 60.89
\$ 70.01-\$80.00	0.4	6.5	\$ 72.27	0.3	\$ 72.33
	<b>29.7</b>	<b>6.6</b>	<b>\$ 33.51</b>	<b>18.3</b>	<b>\$ 31.70</b>

In June 2001, the Company introduced an employee stock purchase plan ("ESPP") under which 3.0 million shares of common stock were reserved for issuance. Eligible employees may purchase a limited number of shares of the Company's common stock at 85% of the market value at plan-defined dates. Employees purchased 206,176 shares, 163,345 shares, and 43,976 shares for \$4.8 million, \$4.0 million, and \$1.5 million during 2003, 2002, and 2001 respectively, under the plan.

69

In connection with the Acquisition, the Company assumed outstanding warrants to purchase common stock, which are as follows as of December 31, 2003:

Shares (in 000's)	Exercise Price	Expiration
365.5	\$ 9.30	February 2007
53.8	\$ 9.30	March 2008
<b>419.3</b>		

Under an agreement assumed in the Acquisition, the Company is also obligated to issue a warrant to purchase 5,147 shares of common stock at an exercise price of \$55.13.

**14. INCOME TAXES**

The components of the provision for income taxes are as follows (in millions):

	Year ended December 31,		
	2003	2002	2001
Current:			
Federal	\$ 33.0	\$ (1.9)	\$ 3.3

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

	Year ended December 31,		
	<u>                    </u>		
State	7.4		
Foreign	0.2	0.1	0.3
	<u>          </u>	<u>          </u>	<u>          </u>
Total current expense (benefit)	40.6	(1.8)	3.6
	<u>          </u>	<u>          </u>	<u>          </u>
Deferred:			
Federal	83.1	48.7	71.1
State	(15.7)	1.3	4.8
Foreign			
	<u>          </u>	<u>          </u>	<u>          </u>
Total deferred expense	67.4	50.0	75.9
	<u>          </u>	<u>          </u>	<u>          </u>
Total tax expense	\$ 108.0	\$ 48.2	\$ 79.5
	<u>          </u>	<u>          </u>	<u>          </u>

Deferred income taxes reflect the net tax effects of the temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax

70

purposes. Significant components of the Company's deferred tax assets and liabilities at December 31, are as follows (in millions):

	2003	2002
	<u>          </u>	<u>          </u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 135.7	\$ 194.7
U.S. general business credit carryforwards	34.7	46.8
Accrued expenses not currently deductible	29.0	28.6
Property and equipment	13.2	13.3
Accounts receivable allowances and reserves	26.7	13.0
Deferred compensation	6.8	7.0
Deferred revenue	8.4	1.5
Prepaid and long term debt	4.3	5.4
California capitalized research expenses	2.4	4.1
Other	5.1	9.9
	<u>          </u>	<u>          </u>
Total deferred tax assets	266.3	324.3
	<u>          </u>	<u>          </u>
Deferred tax liabilities:		
Unrealized gains on investments	(15.0)	(13.5)
Acquired intangibles	(27.8)	(30.7)
	<u>          </u>	<u>          </u>
Total deferred tax liabilities	(42.8)	(44.2)
	<u>          </u>	<u>          </u>
Valuation allowance	(42.9)	(32.3)
	<u>          </u>	<u>          </u>
Net deferred tax assets	\$ 180.6	\$ 247.8

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

2003	2002
<u>          </u>	<u>          </u>
<u>          </u>	<u>          </u>

The provision (benefit) for income taxes varies from the income taxes provided based on the federal statutory rate (35%) as follows:

	Year ended December 31,		
	2003	2002	2001
Tax at U.S. federal statutory rate	35.0%	(35.0)%	35.0%
State taxes, net of federal benefit	(0.2)	0.3	0.7
Change in valuation allowance	3.7	0.2	
Nondeductible in-process R&D		39.3	
U.S. general business credits	(0.8)	(0.4)	(2.1)
Effect of foreign operations		0.1	
Change in state statutory rate			1.1
Other	(0.6)	0.1	0.1
	<u>          </u>	<u>          </u>	<u>          </u>
Total	37.1%	4.6%	34.8%
	<u>          </u>	<u>          </u>	<u>          </u>

At December 31, 2003 the Company had consolidated net operating loss carryforwards for U.S. income tax purposes of approximately \$300 million expiring between 2010 and 2021. The Company also has U.S. general business credit carryforwards comprised of federal research and experimentation and orphan drug credit carryforwards of approximately \$48 million at December 31, 2003 expiring through 2023. Included in the 2003 current tax expense is a benefit of \$16.7 million related to the exercise of employee stock options, which was recorded directly to paid-in-capital. The timing and manner in which the Company will utilize the net operating loss and general business credit carryforwards in any year, or in total, will be limited by provisions of the Internal Revenue Code Sections 382 and 383, regarding changes in ownership of the Company.

71

Deferred taxes are not provided for the earnings of the Company's foreign subsidiaries, as those earnings are considered permanently reinvested in the operations of the foreign subsidiaries and the Company intends to continue to reinvest its undistributed international earnings to expand its international operations. It is not practicable to estimate the amount of additional tax that might be payable on the foreign earnings should they become subject to U.S. tax. Additionally, at December 31, 2003, the Company had foreign net operating loss carryforwards of \$30.7 million for U.K. income tax purposes. The Company has provided a full valuation allowance against foreign net operating losses since realization of these tax benefits cannot be reasonably assured.

The change in the valuation allowance was a net increase of \$10.7 million and \$17.8 million in 2003 and 2002, respectively. The changes in 2003 are primarily comprised of adjustments for the Company's state net operating losses. The changes in 2002 relate primarily to acquired losses and tax credits from the Company's subsidiary, MedImmune Vaccines. The portion of the valuation allowance for which subsequently recognized tax benefits will be applied to reduce goodwill was \$15.6 million at December 31, 2002. During 2003, certain adjustments were made to the deferred tax asset that arose on the acquisition of Aviron, resulting in adjustments to goodwill.

Because management is uncertain of the realization of the tax benefit associated with a portion of the deferred tax assets attributable to the state net operating losses, foreign net operating losses, and the general business credits which were generated by the Company's subsidiary, MedImmune Oncology (formerly U.S. Bioscience, Inc.) prior to its acquisition by the Company, a full valuation allowance remains for these deferred tax assets at December 31, 2003 and 2002.

#### 15. COLLABORATIVE ARRANGEMENTS

**Abbott Laboratories** The Company has entered into a co-promotion agreement with the Ross Product division of Abbott Laboratories for promotion of Synagis in the U.S. and a distribution agreement with Abbott International to distribute Synagis outside of the United States. Under the terms of the co-promotion agreement, the Company is required to pay Abbott an increasing percentage of net domestic sales based on achieving certain sales thresholds over the annual contract year. Under the terms of the distribution agreement, the Company manufactures and sells Synagis to Abbott International at a price based on end-user sales. During 2001, the Company revised its estimate of the total cost to fulfill

its obligations under the agreement, and recorded the cumulative effect of this change in estimate, which resulted in the recognition of additional revenues of \$3.6 million during the year ended December 31, 2001. The Company recognized \$7.5 million in revenues during 2003 for the achievement of certain sales goals, and could receive an additional \$7.5 million in sales goal payments under the agreement.

**ALZA Corporation** In October 2001, the Company reacquired the domestic marketing rights to Ethyol from ALZA Corporation, and recorded termination fees of \$13.4 million to selling, general and administrative expense. Beginning October 1, 2001, the Company records all revenues from domestic sales of Ethyol, and beginning April 1, 2002, the Company pays ALZA a declining royalty for nine years, based on sales of Ethyol in the United States.

**Evans Vaccines Limited** The Company manufactures key components of FluMist, specifically the bulk monovalents and diluent, at a facility in Speke, the United Kingdom, pursuant to a sublease arrangement with Evans Vaccines Limited, a division of Chiron. The manufacturing areas on the existing site are subleased through June 2006. In connection with the agreements, the Company made an initial payment of \$15.0 million and additional payments of \$3.9 million each in September 2001, 2002 and 2003. The Company is obligated to make two additional annual payments of \$3.9 million in September 2004 and September 2005, which are included in other current liabilities and Obligations to Evans in the accompanying consolidated balance sheet as of December 31, 2003. The Company is also obligated to make additional payments of \$19 million, less accrued interest, which will be paid over the

72

---

term of the agreement based on net sales of FluMist, with the unpaid balance, if any, due January 2006.

**GlaxoSmithKline (GSK)** The Company and GSK are developing a vaccine against human papillomavirus ("HPV") to prevent cervical cancer under a strategic alliance. Under the terms of the agreement, the companies will collaborate on research and development activities. The Company conducted Phase 1 and Phase 2 clinical trials and manufactures clinical material for the studies. GSK is responsible for the final development of the product, as well as regulatory, manufacturing, and marketing activities. In exchange for exclusive worldwide rights to the Company's HPV technology, GSK agreed to provide the Company with an up front payment of \$15 million, research funding of \$23 million through 2002, potential developmental and sales milestones which together could total up to \$48 million in the future, as well as royalties on any product sales and an equity investment of \$5 million. Research funding of \$0.5 million, \$0.2 million and \$2.8 million associated with the agreement has been included in other revenues for the years ended December 31, 2003, 2002, and 2001, respectively.

In 2000, the Company granted a worldwide, exclusive license to its *Streptococcus pneumoniae* vaccine technology to GSK in exchange for an up front payment of \$10 million and future milestones totaling more than \$20 million, plus royalties on any product sales. Under the terms of the agreement, GSK is responsible for all clinical development, manufacturing and sales and marketing activities for the *S. pneumoniae* vaccine.

The Company has rights to a vaccine against certain subunits of Epstein-Barr virus ("EBV"), a herpesvirus that is the leading cause of infectious mononucleosis. The vaccine is being developed by GSK under a worldwide collaborative agreement, excluding North Korea and South Korea. Under the agreement, the Company could receive future milestone payments, and royalties from GSK based on any net product sales.

**Schering-Plough Corporation** The Company has entered into a collaboration arrangement with affiliates of Schering-Plough Corporation (Schering), for distribution of Ethyol in countries comprising the European Union, the European Free Trade Association and other countries outside of the U.S. Schering's exclusive rights to market the product continued through December 31, 2003, and the Company may co-promote Ethyol with Schering for two years, through December 31, 2005. Thereafter, the Company will reacquire sole marketing rights, subject to an obligation to pay Schering a royalty based on a percentage of net sales, if any, from the European territories for a period of three years.

The Company also entered into licensing agreements for Ethyol and NeuTrexin with affiliates of Schering for several territories outside the United States. The licensees are required to pay the Company compensation based on their net sales of the products, and the Company sells the products to the licensees at an agreed upon price.

**Wyeth** The Company has entered into a set of complex collaboration agreements with Wyeth related to intranasally delivered live, attenuated influenza virus vaccine products. FluMist is the subject of the collaborative arrangement with Wyeth. FluMist is manufactured by the Company, distributed in the U.S. exclusively by Wyeth, and co-promoted in the U.S. by the Company and Wyeth. Outside of the U.S., Wyeth has exclusive worldwide rights to FluMist worldwide, excluding Australia, New Zealand, North Korea, South Korea, and some South Pacific countries. The parties amended the agreements in September 2003, including modifications to the formula used to calculate the product transfer payments from Wyeth to the Company, and adjustments to the optional term extension and related payment provisions in the U.S. and international territories.

Wyeth holds the marketing rights in the United States for eleven years from the first commercial sale of FluMist. Outside the United States (with the exclusions noted above), Wyeth holds the marketing rights for an initial term of eight years from the first international commercial sale of

FluMist. Under the terms of the agreement with Wyeth, the two companies are to collaborate on the regulatory, clinical and marketing programs for FluMist within the United States.

Under the terms of the agreement, Wyeth distributes FluMist and records all product sales. The Company is paid in the form of product transfer payments and royalties, which are higher in the United States than internationally. The Company shipped approximately 4.1 million doses of FluMist to Wyeth during 2003, but did not recognize any sales-related revenue in 2003 due to the lack of certainty associated with returns and discounts in the vaccine's launch season. The Company incurs expenses to manufacture, supply and co-promote FluMist. There is potential for the manufacturing cost incurred by the Company to exceed transfer payments received from Wyeth. Wyeth reimburses the Company for a portion of the product's clinical development and sales and marketing expenses, and anticipates spending up to \$100 million over the first three years for commercialization of FluMist in the United States. During 2003, the Company received \$8.4 million in reimbursements from Wyeth for marketing expenses, which is included in other revenues.

As a part of the collaboration, the Company is to receive certain payments related to the achievement of key milestones and events for FluMist. During 2003, the Company received \$37.5 million for FDA approval in the United States, for achieving the supply goal in the first season, and for achieving ACIP guideline recommendations. In December 2002, the Company received \$25.0 million from Wyeth as compensation for manufacturing costs incurred in preparing for the then-expected 2002 FluMist launch. Under the agreements, as amended, potential future milestones and related payments to the Company from Wyeth include: \$15 million for advisory body recommendations and expanded label claims; an additional \$12.5 million in supply goal payments; up to \$17.5 million for FDA approval of use in multiple target populations; \$10 million for the submission of a license application in Europe; \$27.5 million for FDA approval of a liquid formulation of FluMist; and up to \$50 million upon licensure in international regions. Additionally, Wyeth is committed to provide the Company with up to \$20 million in financing, contingent upon regulatory approval of FluMist. The total potential future value for the license fees, milestones, financing support and term extension options that the Company could receive from Wyeth could range from approximately \$153 million to \$190 million.

In general, the Company and Wyeth share responsibility for clinical development of intranasally delivered live, attenuated influenza virus vaccine products. A liquid, refrigerator-stable version of the trivalent, live, attenuated, cold-adapted influenza virus vaccine, CAIV-T, is being developed under the collaborative agreement with Wyeth. CAIV-T may have the potential to replace FluMist (a frozen vaccine) since frozen vaccines pose distribution and commercial challenges. Wyeth has been conducting late-stage clinical trials with CAIV-T and has begun collecting and evaluating that data. In connection with the 2003 amendments, the Company agreed to pay \$10 million to Wyeth for the purchase and use of clinical trial data from Wyeth's international CAIV-T trials.

**Other Agreements** The Company has entered into research, development and license agreements with various federal and academic laboratories and other institutions to further develop its products and technology and to perform clinical trials. Under these agreements, the Company is obligated to provide funding and milestone payments of approximately \$7.2 million in 2004, and \$16.3 million in the aggregate upon the occurrence of certain events in the future, such as the granting by the FDA of a license for product marketing in the United States. In exchange for the licensing rights for commercial development of proprietary technology, the Company has agreed to pay royalties on sales using such licensed technologies.

## **16. COMMITMENTS AND CONTINGENCIES**

**Manufacturing, Supply and Purchase Agreements** The Company has entered into manufacturing, supply and purchase agreements to provide production capability for CytoGam and RespiGam, and to

provide a supply of human plasma for production of both products. The Company has an agreement with BioLife Plasma Services and is committed to purchase \$7.7 million of source plasma in 2004. No assurance can be given that an adequate supply of plasma will be available from the Company's suppliers. Prior to November 2002, human plasma for CytoGam was converted to an intermediate (Fraction II+III paste) at the FMC. Effective November 2002, the Company contracted Precision Pharma Services to manufacture all of the Company's Fraction II+III



paste. The Company paid Precision Pharma Services \$2.4 million in 2003. The intermediate material is then supplied to the manufacturer of the bulk product, MBL. The Company paid MBL \$8.1 million in 2003. Pursuant to the agreements with MBL, the Company paid \$3.2 million in 2002, and \$6.8 million in 2001 for production and process development. The Company has a commercial agreement with MBL for planned production of CytoGam through June 2006 for \$14.0 million, subject to production level adjustments. Because RespiGam has been replaced in the marketplace by the Company's second generation product, Synagis, the manufacture of RespiGam has been discontinued as of the end of 2003. If MBL, which holds the sole product and establishment licenses from the FDA for the manufacture of CytoGam is unable to satisfy the Company's requirements for CytoGam on a timely basis or is prevented for any reason from manufacturing CytoGam, the Company may be unable to secure an alternative manufacturer without undue and materially adverse operational disruption and increased cost.

In December 1997, the Company entered into an agreement with BI, to provide supplemental manufacturing of the Company's second generation RSV product, Synagis. The Company has a firm commitment for \$6.5 million in 2004 with BI for the filling, finishing and packaging of Synagis product manufactured at the FMC. The Company paid \$18.1 million in 2003, \$6.7 million in 2002, and \$14.3 million in 2001 related to production and scale-up of production as part of an additional agreement. The Company has firm commitments with BI for planned production through 2012 for approximately \$92.1 million. Should the manufacturer be unable to supply Synagis to the Company for any reason, there can be no assurance that the Company will be able to secure an alternate manufacturer in a timely basis or without increased cost.

In August 1998, the Company signed a worldwide multi-year supply agreement with Becton Dickinson for the supply of its AccuSpray non-invasive nasal spray delivery system for administration of FluMist. The Company has firm commitments with Becton Dickinson for future purchases of sprayers of \$3.8 million in both 2004 and 2005.

In August 2000, the Company entered into a production agreement with Packaging Coordinators, Inc. ("PCI"), to perform secondary production (i.e., assembly, labeling and packaging) of FluMist. As part of this agreement, the Company is obligated to pay PCI annual non-refundable minimum payments for each contract year, if the price for units invoiced to the Company during a production year totals less than the minimum payment. Payments of \$1.1 million were made for each of the years 2002 and 2001. The Company amended its agreement with Cardinal Health 406, Inc., formerly known as PCI, in December 2003. Future minimum payments totaling \$4.2 million are committed through December 31, 2006. Should the actual level of future production exceed the contract minimum, then actual payments will be correspondingly higher.

The Company has issued irrevocable standby letters of credit to guarantee performance under certain agreements related to the construction project for the Company's new headquarters and research and development facility. The undiscounted maximum potential amount of future payments that the Company could be required to make under such guarantees, in the aggregate, is approximately \$2.2 million.

## **17. LEGAL PROCEEDINGS**

In October 2000, Celltech Chiroscience Limited ("Celltech") commenced a legal proceeding against the Company in the U.K. in which it alleged that the Company failed to pay royalties with

75

---

respect to its sales of Synagis as required by a license agreement dated January 19, 1998. Under the agreement, the Company obtained from Celltech a worldwide license to make, use and/or sell product under a patent (and related applications) pertaining to humanized antibodies. In the proceeding, Celltech sought payment of a 2% royalty based on net sales of Synagis sold or manufactured in the United States, with interest, and certain costs, including attorney's fees. In October 2002, the UK Court ruled in the Company's favor and dismissed Celltech's case. That dismissal was upheld on appeal in July 2003. Celltech sought appellate review by the House of Lords, and that request was denied in January 2004, bringing an end to this particular litigation.

In September 2002, Celltech commenced a second legal proceeding against the Company in the U.K. Celltech seeks payment of a 2% royalty based on net sales of Synagis sold or manufactured in Germany, with interest and certain costs, including attorney fees. The Company filed answering papers in December 2002 denying that it owes the royalties that Celltech seeks through its second proceeding. This matter is scheduled for trial before the UK High Court of Justice in March 2004. To date, the Company has not made the royalty payments that were the subject of its September 2002 lawsuit.

The Company has become aware that a new United States patent was issued on October 14, 2003 in the name of Celltech Therapeutics Limited, which the Company understands is an affiliated entity of Celltech (the "Adair Patent"). If the manufacture or sale of Synagis® or any of the Company's other products is ultimately found to be covered by any valid claim of this new patent and/or any other Celltech patent that is the subject of the license agreement with Celltech, the Company's total royalty obligation would equal 2% of the net sales of the products that are so covered. To date, the Company has not made any royalty payments to Celltech under the license agreement with Celltech. In January 2004, the

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

Company filed a declaratory judgment action in the United States District Court for the District of Columbia concerning the Adair patent and alleging patent invalidity and non-infringement with regard to Synagis.

In April 2002, the Company filed a suit against Centocor, Inc. ("Centocor") in the United States District Court for the District of Maryland. That action was amended in January 2003 to add the Trustees of Columbia University in the City of New York ("Columbia") and the Board of Trustees of the Leland Stanford University ("Stanford") as the owners of the patent. The Company currently pays Centocor a royalty for sales of Synagis made or sold in the United States pursuant to a patent Sublicense Agreement between the parties (the "Sublicense Agreement"). In the litigation, the Company seeks a declaratory judgment that it has no obligation to continue paying royalties to Centocor on the basis that the patent is invalid, unenforceable and does not cover Synagis. Additionally, the Company seeks an injunction preventing Centocor from enforcing this patent. This matter is ongoing and no trial date is scheduled.

In January 2003, a lawsuit was filed by the County of Suffolk, New York ("Suffolk") in the United States District Court, Eastern District of New York, naming the Company along with approximately 25 other pharmaceutical and biotechnology companies as defendants. In August 2003, the County of Westchester, New York ("Westchester") filed and served a similar suit against the Company and approximately 25 other pharmaceutical and biotechnology defendants. Likewise, in September 2003, the County of Rockland, New York ("Rockland") also filed and served a similar suit against the Company and approximately 25 other pharmaceutical and biotechnology defendants. Suffolk, Westchester and Rockland allege that the defendants manipulated the "average wholesale price" ("AWP") causing the Counties to pay artificially inflated prices for covered drugs. In addition, the Counties argue that the defendants (including the Company) did not accurately report the "best price" under the Medicaid program. The plaintiffs seek declaratory and injunctive relief, disgorgement of profits, treble and punitive damages suffered as a result of defendants' alleged unlawful practices related prescription medication paid for by Medicaid. All three of these cases have been consolidated (for pre-trial purposes) and transferred to the United States Court for the District of Massachusetts in Re: Pharmaceutical Industry Average Wholesale Price Litigation (AWP Multidistrict Litigation). A Motion

76

---

to dismiss the complaint against the Company relative to the County of Suffolk has been argued before the Court and a decision is pending.

In April 2003, the Company filed a suit against Genentech, Inc. ("Genentech"), Celltech R&D Ltd. and City of Hope National Medical Center ("City of Hope") in the United States District Court for the Central District of California. The Company currently pays Genentech a royalty for sales of Synagis® made or sold in the United States pursuant to a patent license agreement between the parties covering United States Patent No. 6,331,415B1 (the "Cabilly Patent"). In the complaint, the Company alleges that the Cabilly Patent was obtained as a result of a collusive agreement between Genentech and Celltech that violates federal and California antitrust laws as well as California's unfair business practices act. Additionally, the Company alleges that the Cabilly Patent is invalid and unenforceable under federal patent law and is not infringed. The Company thus seeks a declaration that it owes no royalty payments under existing licensing agreements with Genentech. In December 2003, the court granted motions filed by Celltech and Genentech to dismiss the federal and California antitrust claims and claims under California's unfair business practices act. Discovery is proceeding relative to the allegations in the suit that the Cabilly patent is invalid and unenforceable under federal patent law and is not infringed by Synagis.

The Company is also involved in other legal proceedings arising in the ordinary course of its business. After consultation with its legal counsel, the Company believes that it has meritorious defenses to the claims against it referred to above and is determined to defend its position vigorously. While it is impossible to predict with certainty the eventual outcome of these proceedings, the Company believes they are unlikely to have a material adverse effect on its financial position but might have a material adverse effect on its results of operations for a particular period. There can be no assurance that the Company will be successful in any of the litigation it has initiated. In its ordinary course of business, the Company has provided indemnification to various parties for certain product liability claims and claims that the Company's products were not manufactured in accordance with applicable federal standards. While the Company is not aware of any current claims under these provisions, there can be no assurance that such claims will not arise in the future or that the effect of such claims will not be material to the Company.

77

---

### REPORT OF INDEPENDENT AUDITORS

To the Board of Directors and Shareholders of MedImmune, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of cash flows and of shareholders' equity present fairly, in all material respects, the financial position of MedImmune, Inc. and its subsidiaries at December 31, 2003

and December 31, 2002, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 2 to the financial statements, the Company changed its method of revenue recognition for contract revenues, effective January 1, 2002.

/s/ PRICEWATERHOUSECOOPERS LLP

---

McLean, Virginia  
February 13, 2004, except for Note 10  
as to which the date is February 25, 2004

78

---

#### REPORT OF MANAGEMENT

The management of the Company is responsible for the preparation of the financial statements and related financial information included in this annual report. The statements were prepared in conformity with accounting principles generally accepted in the United States of America and, accordingly, include amounts that are based on informed estimates and judgments.

Management maintains a system of internal controls to provide reasonable assurance that assets are safeguarded and that transactions are properly authorized and accurately recorded. The concept of reasonable assurance is based on the recognition that there are inherent limitations in all systems of internal accounting control and that the costs of such systems should not exceed the benefits expected to be derived. The Company continually reviews and modifies these systems, where appropriate, to maintain such assurance. The system of internal controls includes careful selection, training and development of operating and financial personnel, well-defined organizational responsibilities and communication of Company policies and procedures throughout the organization.

The selection of the Company's independent accountants, PricewaterhouseCoopers LLP, has been approved by the Audit Committee of the Board of Directors and ratified by the Board of Directors and the shareholders. The Audit Committee of the Board of Directors, comprised solely of outside directors, meets periodically with the Company's independent accountants and management to review the financial statements and related information and to confirm that they are properly discharging their responsibilities. In addition, the independent accountants and the Company's legal counsel meet with the Audit Committee, without the presence of management, to discuss their findings and their observations on other relevant matters. Recommendations made by PricewaterhouseCoopers LLP are considered and appropriate action is taken to respond to these recommendations.

/s/ DAVID M. MOTT

---

David M. Mott  
*Chief Executive Officer, President and Vice Chairman*

/s/ LOTA S. ZOTH

---

Lota S. Zoth  
*Vice President and Controller, Acting Chief  
Financial Officer*

#### ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

##### ITEM 9A. CONTROLS AND PROCEDURES

The Company maintains disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Vice Chairman, President and Chief Executive Officer and Vice President, Controller and Acting Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable, and not absolute, assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible

79

---

controls and procedures. Accordingly, no evaluation or implementation of a control system can provide complete assurance that all control issues and all possible instances of fraud have been or will be detected.

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Vice Chairman, President and Chief Executive Officer and Vice President, Controller and Acting Chief Financial Officer, of the effectiveness of the Company's disclosure controls and procedures, as required by Rule 13a-15(b) promulgated under Exchange Act. Based upon that evaluation, the Company's Vice Chairman, President and Chief Executive Officer and Vice President, Controller and Acting Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective at the reasonable assurance level.

In addition, the management of the Company, with the participation of the Company's Vice Chairman, President and Chief Executive Officer and Vice President, Controller and Acting Chief Financial Officer, have determined that there was no change in the Company's internal control over financial reporting that occurred during Q4 2003 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

### **PART III**

#### **ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF MEDIMMUNE, INC.**

Information with respect to directors is included in the Company's Proxy Statement to be filed pursuant to Regulation 14A (the "Proxy Statement") under the caption "Election of Directors," and such information is incorporated herein by reference. Set forth in Part I, Item 1, are the names and ages (as of May 20, 2004), the positions and offices held by, and a brief account of the business experience during the past five years of each executive officer. All directors hold office until the next annual meeting of shareholders and until their successors are elected and qualified. Officers and key employees are elected to serve, subject to the discretion of the Board of Directors, until their successors are appointed.

#### **ITEM 11. EXECUTIVE COMPENSATION**

The section entitled "Executive Compensation" and the information set forth under the caption "Election of Directors-Director Compensation" included in the Proxy Statement are incorporated herein by reference.

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The common stock information in the section entitled "Principal Shareholders" of the Proxy Statement is incorporated herein by reference.

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

The section entitled "Certain Transactions" of the Proxy Statement is incorporated herein by reference.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this item is incorporated by this item is incorporated by reference to the applicable information in the 2004 Proxy Statement under the caption "Appointment of Independent Auditors."

80

---

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULE AND REPORTS ON FORM 8-K**

The following documents or the portions thereof indicated are filed as a part of this report.

- a) Documents filed as part of the Report
1. Financial Statements and Supplemental Data
    - a. Consolidated Balance Sheets at December 31, 2003 and 2002
    - b. Consolidated Statements of Operations for the years ended December 31, 2003, 2002, and 2001
    - c. Consolidated Statements of Cash Flows for the years ended December 31, 2003, 2002, and 2001
    - d. Consolidated Statements of Shareholders' Equity for the years ended December 31, 2003, 2002, and 2001
    - e. Notes to Consolidated Financial Statements
    - f. Report of Independent Auditors
    - g. Report of Management
  2. Supplemental Financial Statement Schedule  
Report of Independent Auditors on Financial Statement Schedule  

Schedule I Valuation and Qualifying Accounts Page S-1

- b) Reports on Form 8-K:

<b>Date Filed</b>	<b>Event Reported</b>
October 23, 2003	MedImmune reports record revenues for 2003 third quarter and nine-month period.

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

<u>Date Filed</u>	<u>Event Reported</u>
November 18, 2003	MedImmune provides update to FluMist launch and revises guidance for fourth quarter and full year.

c)

ITEM 601 EXHIBITS

Those exhibits required to be filed by Item 601 of Regulation S-K are listed in the Exhibit Index beginning on page E1 and such listing is incorporated by reference.

81

---

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MEDIMMUNE, INC.

Date: March 9, 2004

/s/ DAVID M. MOTT

---

David M. Mott  
*Chief Executive Officer, President, and Vice Chairman  
Principal Executive Officer*

Date: March 9, 2004

/s/ LOTA S. ZOTH

---

Lota S. Zoth  
*Vice President, Controller and Acting Chief Financial Officer  
Principal Accounting and Financial Officer*

82

---

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons in the capacities and on the dates indicated.

Date: March 9, 2004

/s/ WAYNE T. HOCKMEYER

---

Wayne T. Hockmeyer, Chairman

Date: March 9, 2004

/s/ M. JAMES BARRETT

---

M. James Barrett, Director

Date: March 9, 2004

/s/ MELVIN D. BOOTH

---

Melvin D. Booth, Director

Date: March 9, 2004

/s/ JAMES H. CAVANAUGH

---

James H. Cavanaugh, Director

Date: March 9, 2004 /s/ BARBARA HACKMAN FRANKLIN  
\_\_\_\_\_  
 Barbara Hackman Franklin, Director

Date: March 9, 2004 /s/ GORDON S. MACKLIN  
\_\_\_\_\_  
 Gordon S. Macklin, Director

Date: March 9, 2004 /s/ ELIZABETH WYATT  
\_\_\_\_\_  
 Elizabeth Wyatt, Director

Date: March 9, 2004 /s/ DAVID BALTIMORE  
\_\_\_\_\_  
 David Baltimore, Director

**REPORT OF INDEPENDENT AUDITORS ON FINANCIAL STATEMENT SCHEDULE**

To the Board of Directors and Shareholders of MedImmune, Inc.:

Our audits of the consolidated financial statements referred to in our report dated February 13, 2004, except for Note 10, as to which the date is February 25, 2004, appearing in this Annual Report on Form 10-K also included an audit of the financial statement schedule listed in Item 15(a)(2) of this Form 10-K. In our opinion, the financial statement schedule presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements.

/s/ PRICEWATERHOUSECOOPERS LLP  
 McLean, Virginia  
 February 13, 2004

**SCHEDULE I**

**MedImmune, Inc.**  
**Valuation and Qualifying Accounts**  
**(in thousands)**

Description	Balance at beginning of period	Additions	Deductions	Balance at end of period
For the year ended December 31, 2003				
Sales Allowances	\$ 10,596	\$ 74,464	\$ (76,105)	\$ 8,955
Trade Receivables Bad Debt Reserve	7,468	28,760	(32,425)	3,803
Inventory Reserve	51,132	179,561	(142,546)	88,147
Physical Asset Reserve	305			305
	<u>\$ 69,501</u>	<u>\$ 282,785</u>	<u>\$ (251,076)</u>	<u>\$ 101,210</u>
For the year ended December 31, 2002				

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

Description	Balance at beginning of period	Additions	Deductions	Balance at end of period
Sales Allowances	\$ 6,891	\$ 10,086	\$ (6,381)	\$ 10,596
Trade Receivables Bad Debt Reserve	2,520	4,948		7,468
Inventory Reserve	9,140	73,921	(31,929)	51,132
Physical Asset Reserve	2,374	71	(2,140)	305
	<u>\$ 20,925</u>	<u>\$ 89,026</u>	<u>\$ (40,450)</u>	<u>\$ 69,501</u>
For the year ended December 31, 2001				
Sales Allowances	\$ 5,698	\$ 3,773	\$ (2,580)	\$ 6,891
Trade Receivables Bad Debt Reserve	1,562	1,095	(137)	2,520
Inventory Reserve	6,230	12,703	(9,793)	9,140
Physical Asset Reserve	2,463		(89)	2,374
	<u>\$ 15,953</u>	<u>\$ 17,571</u>	<u>\$ (12,599)</u>	<u>\$ 20,925</u>

S-1

**ITEM 601 EXHIBITS**

- 3.1 Restated Certificate of Incorporation, as restated as of February 25, 2004.\*
- 3.2 By-Laws, as amended and restated as of February 25, 2004.\*
- 4.1 Amended and Restated Rights Agreement, dated as of October 31, 1998, between MedImmune, Inc., and American Stock Transfer and Trust Company, as Rights Agent, incorporated by reference to Exhibit 99.2 filed with the Company's Registration Statement on Form 8A/A, filed with the Securities and Exchange Commission on December 1, 1998.
- 4.2 Certificate of Designations of Series B Junior Preferred Stock, incorporated by reference to exhibit 4.2 filed with the Company's Annual Report on Form 10-K for December 31, 2001.
- 4.3 Warrant for Common Stock, issued to University of Michigan, incorporated by reference to Exhibit 4.14 to Aviron's Annual Report on Form 10-K for the year ended December 31, 1999.
- 4.4 Indenture entered into between Aviron and HSBC Bank USA as Trustee, dated February 7, 2001, incorporated by reference to Exhibit 4.22 to Aviron's Annual Report on Form 10-K405 for the year ended December 31, 2000.
- 4.5 Officer's Certificate pursuant to Section 2.01 of the Subordinated Indenture, dated February 7, 2001, incorporated by reference to Exhibit 4.22 to Aviron's Annual Report on Form 10-K405 for the year ended December 31, 2000.
- 4.6 Warrant for Common Stock, issued to University of Michigan, incorporated by reference to Exhibit 4.25 to Aviron's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.
- 10.1 RSV License Agreement dated August 1, 1989 between the Company, PPI and MHRI, incorporated by reference to exhibit 10.5 filed in connection with the Company's Registration Statement No. 33-39579.
- 10.2 RSV Supply Agreement dated August 1, 1989 between the Company, PPI, MHRI and the Massachusetts Public Health Biologic Laboratory ("MPHBL"), incorporated by reference to exhibit 10.6 filed in connection with the Company's Registration Statement No. 33-39579.
- 10.3 License Agreement dated November 8, 1989 between the Company, PPI, and the Henry M. Jackson Foundation for the Advancement of Military Medicine ("HMJ"), incorporated by reference to exhibit 10.10 filed in connection with the Company's Registration Statement No. 33-39579.
- 10.4 Agreement dated October 26, 1995 between American Cyanamid Company and the Company, related to the RSV MAB Co-Development and Co-Promotion Agreement between American Cyanamid Company and the Company dated November 8, 1993, incorporated by reference to exhibit 10.37.1 filed in connection with the Company's Annual Report on Form 10-K for December 31, 1995.
- 10.5(1)



## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

- Patent License Agreement, (MEDI-493) dated July 17, 1997 by and between Protein Design Labs and MedImmune, Inc., incorporated by reference to exhibit 10.73 filed with the Company's Quarterly Report on Form 10-Q for the Quarter ended September 30, 1997.
- 10.6(1) License Agreement, dated June 4, 1997, between Genentech, Inc. and MedImmune, Inc., incorporated by reference to exhibit 10.180 filed with the Company's Annual Report on Form 10-K for December 31, 2002.

E1

- 
- 10.7(1) License for Winter Patent, dated August 13, 1997, between Medical Research Council and MedImmune, Inc., incorporated by reference to exhibit 10.181 filed with the Company's Annual Report on Form 10-K for December 31, 2002.
- 10.8(1) Biological Materials License Agreement, effective as of August 24, 1997, between Public Health Service through the Office of Technology Transfer, National Institutes of Health, and MedImmune, Inc., incorporated by reference to exhibit 10.182 filed with the Company's Annual Report on Form 10-K for December 31, 2002.
- 10.9(1) License Agreement, dated effective December 1, 1997, between the University of Iowa Research Foundation and MedImmune, Inc., incorporated by reference to exhibit 10.183 filed with the Company's Annual Report on Form 10-K for December 31, 2002.
- 10.10(1) Sublicense Agreement between Centocor, Inc. and MedImmune, Inc., incorporated by reference to exhibit 10.174 filed with the Company's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2002.
- 10.11(1) License Agreement and Amendment to RSV License Agreement, dated December 16, 2002, between MedImmune, Inc. and the Massachusetts Biologic Laboratories of the University of Massachusetts, incorporated by reference to exhibit 10.184 filed with the Company's Annual Report on Form 10-K for December 31, 2002.
- 10.12(1) Co-Promotion Agreement between Abbott Laboratories and MedImmune, Inc. dated November 26, 1997, incorporated by reference to exhibit 10.76 filed with the Company's Annual Report on Form 10-K for December 31, 1997, as amended by the Amendment effective as of November 26, 1997, incorporated by reference to exhibit 10.23.1 filed with the Company's Annual Report on Form 10-K for December 31, 2002, as further amended by the Amendment No. 2, effective as of November 26, 1997, incorporated by reference to exhibit 10.23.2 filed with the Company's Annual Report on Form 10-K for December 31, 2002.
- 10.13(1) Distribution Agreement between MedImmune, Inc. and Abbott International, Ltd. dated November 26, 1997, incorporated by reference to exhibit 10.79 filed with the Company's Annual Report on Form 10-K for December 31, 1997, as amended by the Amendment effective as of April 28, 1999, incorporated by reference to exhibit 10.26.1 filed with the Company's Annual Report on Form 10-K for December 31, 2002, as further amended by the Second Amendment dated effective as of October 8, 1999, incorporated by reference to exhibit 10.26.2 filed with the Company's Annual Report on Form 10-K for December 31, 2002, as further amended by the Third Amendment dated effective as of July 1, 2003, incorporated by reference to exhibit 10.26.3 filed with the Company's Quarterly Report on Form 10-Q for September 30, 2002.
- 10.14(1) Manufacturing Agreement between MedImmune, Inc. and Dr. Karl Thomae GmbH dated November 27, 1997, incorporated by reference to exhibit 10.78 filed with the Company's Annual Report on Form 10-K for December 31, 1997.
- 10.15(1) Supply Transfer Agreement between Immunex Corporation and MedImmune, Inc., incorporated by reference to exhibit 10.128 filed with the Company's Quarterly Report on Form 10-Q/A for the Quarter ended June 30, 2001.
- 10.16 Amended and Restated License Agreement, effective as of May 1, 1993, between U.S. Bioscience, Inc. and Southern Research Institute, incorporated by reference to Exhibit 10.8 to the U.S. Bioscience, Inc. Annual Report on Form 10-K for December 31, 1993.
- 10.17 License Agreement, dated February 14, 1992, between U.S. Bioscience, Inc. and Schering Overseas Limited, incorporated by reference to Exhibit 10.14 to the U.S. Bioscience, Inc. Annual Report on Form 10-K for December 31, 1992, as amended by the Amendment dated effective October 15, 1993, incorporated by reference to Exhibit 10.14.1 to the U.S. Bioscience, Inc. Annual Report on Form 10-K for December 31, 1993.

E2

- 
- 10.18 Amended and restated License Agreement dated May 10, 1994 between U.S. Bioscience, Inc. and Scherico, Ltd., incorporated by reference to Exhibit 10.15 to the U.S. Bioscience, Inc. Annual Report on Form 10-K for December 31, 1997.
  - 10.19 License Agreement between U.S. Bioscience, Inc. and Scherico, Ltd. dated as of November 6, 1997, incorporated by reference to Exhibit 10.27 to the U.S. Bioscience, Inc. Annual Report on Form 10-K for December 31, 1997, as amended by Amendment No. 1 dated effective as of November 6, 1997, incorporated by reference to Exhibit 10.27.1 to the U.S. Bioscience, Inc. Annual Report on Form 10-K for December 31, 1997.
  - 10.20(2) Amifostine Manufacturing and Supply Agreement, dated as of January 1, 2001 between MedImmune Oncology and PPG Industries, Inc.\*
  - 10.21(2) Terms and Conditions for the Manufacture of Products by Ben Venue Laboratories, Inc., dated as of October 17, 2003.\*
  - 10.22(1) Distribution and Supply Agreement, dated as of May 10, 1993 between U.S. Bioscience, Inc. and Scherico, Ltd., incorporated by reference to Exhibit 10.16 to the U.S. Bioscience, Inc. Annual Report on Form 10-K for December 31, 1994, as amended by the Amendment dated effective August 31, 1996, incorporated by reference to Exhibit 10.16.1 to the U.S. Bioscience, Inc. Current Report on Form 8-K/A dated September 19, 1996.
  - 10.23(1) Ethyol (Amifostine) Distribution and Marketing Collaboration Agreement between U.S. Bioscience, Inc. and ALZA Corporation dated December 12, 1995, incorporated by reference to Exhibit 5 to the U.S. Bioscience, Inc. Current Report on Form 8-K dated December 22, 1995, as amended by the Amendment No. 2, dated effective as of February 3, 1997, incorporated by reference to Exhibit 10.25.2 to the U.S. Bioscience, Inc. Current Report on Form 8-K dated February 3, 1997, as further amended by Amendment No. 3 dated effective as of September 4, 2001, incorporated by reference to exhibit 10.129 filed with the Company's Quarterly Report on Form 10-Q/A for the Quarter ended September 30, 2001.
  - 10.24(1) Materials Transfer and Intellectual Property Agreement between the Registrant and the Regents of the University of Michigan, dated February 24, 1995, incorporated by reference to Exhibit 10.3 to Aviron's Registration Statement on Form S-1 filed with the Securities and Exchange Commission June 5, 1996, as amended by the Letter Amendment dated effective as of February 24, 1999, incorporated by reference to Exhibit 10.24 to Aviron's Quarterly Report on Form 10-Q for the quarter ended March 31, 1999.
  - 10.25 Stock Transfer Agreement between the Registrant and the Regents of the University of Michigan, dated February 24, 1995, incorporated by reference to Exhibit 10.4 to Aviron's Registration Statement on Form S-1 filed June 5, 1996, as amended by Amendment No. 1 dated effective February 16, 2000, incorporated by reference to Exhibit 10.33 to Aviron's Annual Report on Form 10-K for the year ended December 31, 1999, as further amended by Amendment No. 2 dated effective as of March 29, 2001, incorporated by reference to Exhibit 10.52 to Aviron's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.
  - 10.26(1)(2) Facility Reservation Agreement between the Registrant and Packaging Coordinators, Inc., dated as of October 31, 1997, incorporated by reference to Exhibit 10.17 to Aviron's Registration Statement on Form S-3 filed December 5, 1997, as amended by the First Amendment dated effective as of August 1, 2000, incorporated by reference to Exhibit 10.32 to Aviron's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, as further amended by the Second Amendment dated December 31, 2003.\*

E3

- 
- 10.27(1) Biological Materials License Agreement between the Registrant and the National Institutes of Health, dated May 31, 1996, incorporated by reference to Exhibit 10.14 to Aviron's Registration Statement on Form S-1/A filed June 20, 1996.
  - 10.28(1) Supply Agreement between the Registrant and Becton Dickinson dated July 1, 1998, incorporated by reference to Exhibit 10.19 to Aviron's Quarterly Report on Form 10-Q for the quarter ended September 30, 1998.
  - 10.29(1) United States License and Co-Promotion Agreement between the Registrant and Wyeth Lederle Vaccines dated January 11, 1999, incorporated by reference to Exhibit 10.20 to Aviron's Annual Report on Form 10-K for the year ended on December 31, 1998, as amended by the First Amendment, incorporated by reference to exhibit 10.177 filed with the Company's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2002.

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

- 10.30(1) International FluMist License Agreement between the Registrant and Wyeth dated January 11, 1999, incorporated by reference to Exhibit 10.21 to Aviron's Annual Report on Form 10-K for the year ended on December 31, 1998.
- 10.31(1) FluMist Supply Agreement between the Registrant and Wyeth Lederle Vaccines dated January 11, 1999, incorporated by reference to Exhibit 10.22 to Aviron's Annual Report on Form 10-K for the year ended on December 31, 1998, as amended by the FluMist Supply Agreement Amendment dated January 1, 2001, incorporated by reference to Exhibit 10.49 to Aviron's Annual Report on Form 10-K405 for the year ended December 31, 2000, as further amended by the Second Amendment, incorporated by reference to exhibit 10.178 filed with the Company's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2002.
- 10.32(1) Master Amendment Agreement between Registrant and Wyeth dated September 30, 2003, incorporated by reference to exhibit 10.195 filed with the Company's Quarterly Report on Form 10-Q for September 30, 2003.
- 10.33(1) Master Agreement by and between Powderject Pharmaceuticals Limited, Evans Vaccines Limited, the Registrant and Aviron UK, dated October 11, 2000, incorporated by reference to Exhibit 10.44 to Aviron's Annual Report on Form 10-K405 for the year ended December 31, 2000.
- 10.34(1) Agreement Relating to the Sharing and Provision of Certain Services, by and between Evans Vaccines Limited and Aviron UK Limited, incorporated by reference to Exhibit 10.45 to Aviron's Annual Report on Form 10-K405 for the year ended December 31, 2000.
- 10.35(1) Transfer Agreement by and between Evans Vaccines Limited and Aviron UK Limited, dated October 11, 2000, incorporated by reference to Exhibit 10.46 to Aviron's Annual Report on Form 10-K405 for the year ended December 31, 2000.
- 10.36(1) Amended and Restated Contract Manufacture Agreement by and between Evans Vaccines Limited and the Registrant, dated October 11, 2000, incorporated by reference to Exhibit 10.47 to Aviron's Annual Report on Form 10-K405 for the year ended December 31, 2000.
- 10.37(1) Know How License Agreement by and between Evans Vaccines Limited and Aviron UK Limited, dated October 11, 2000, incorporated by reference to Exhibit 10.48 to Aviron's Annual Report on Form 10-K405 for the year ended December 31, 2000.
- 10.38(2) Second Amended and Restated Production Agreement by and between Cardinal Health 406, Inc. and MedImmune Vaccines, Inc., dated December 31, 2003.\*

E4

- 
- 10.39 Lease Agreement between Clopper Road Associates and the Company dated February 14, 1991, incorporated by reference to exhibit 10.22 filed in connection with the Company's Registration Statement No. 33-39579, as amended by the First Amendment dated effective as of June 8, 1993, incorporated by reference to exhibit 10.59 filed with the Company's Annual Report on Form 10-K for December 31, 1996; as further amended by the Second Amendment dated effective June 30, 1993, incorporated by reference to exhibit 10.60 filed with the Company's Annual Report on Form 10-K for December 31, 1996; as further amended by the Third Amendment effective as of January 1, 1995, incorporated by reference to exhibit 10.61 filed with the Company's Annual Report on Form 10-K for December 31, 1996; as further amended by the Fourth Amendment dated October 3, 1996, incorporated by reference to exhibit 10.62 filed with the Company's Annual Report on Form 10-K for December 31, 1996; as further amended by the Fifth Amendment dated October 3, 1996, incorporated by reference to exhibit 10.63 filed with the Company's Annual Report on Form 10-K for December 31, 1996; as further amended by the Sixth Amendment dated September 10, 1997, incorporated by reference to exhibit 10.75 filed with the Company's Annual Report on Form 10-K for December 31, 1997; as further amended by the Seventh Amendment dated effective August 1, 1998, incorporated by reference to exhibit 10.94 filed with the Company's Annual Report on Form 10-K for December 31, 1998.
  - 10.40(1) Agreement for Lease of AVU Premises at Gaskill Road, Speke, dated October 11, 2000, incorporated by reference to Exhibit 10.38 to Aviron's Annual Report on Form 10-K405 for the year ended December 31, 2000.
  - 10.41(1) Underlease of AVU Premises at Gaskill Road Speke, dated October 11, 2000, incorporated by reference to Exhibit 10.39 to Aviron's Annual Report on Form 10-K405 for the year ended December 31, 2000.
  - 10.42(1) Agreement for Lease of AVU Extension Premises at Gaskill Road Speke, dated October 11, 2000, incorporated by reference to Exhibit 10.40 to Aviron's Annual Report on Form 10-K405 for the year ended December 31, 2000.

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

- 10.43(1) Underlease of AVU Extension Premises at Gaskill Road Speke, dated October 11, 2000, incorporated by reference to Exhibit 10.41 to Aviron's Annual Report on Form 10-K405 for the year ended December 31, 2000.
- 10.44(1) Agreement for the Sale and Purchase of Leasehold Property known as Plot 6 Boulevard Industry Park, Halewood, Merseyside, dated October 10, 2000, incorporated by reference to Exhibit 10.42 to Aviron's Annual Report on Form 10-K405 for the year ended December 31, 2000.
- 10.45(1) Underlease of Plot 6 Boulevard Industry Park Halewood Merseyside, dated February 17, 2000, incorporated by reference to Exhibit 10.43 to Aviron's Annual Report on Form 10-K405 for the year ended December 31, 2000.
- 10.46(1) Stipulated Sum Agreement between MedImmune, Inc. and HITT Contracting Inc., incorporated by reference to exhibit 10.175 filed with the Company's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2002.
- 10.47(1) Supplementary General Conditions to the General Conditions of the Contract for Construction Agreement between MedImmune, Inc. and HITT Contracting Inc., incorporated by reference to exhibit 10.176 filed with the Company's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2002.
- 10.48 1991 Stock Option Plan, incorporated by reference to exhibit 10.23 filed in connection with the Company's Registration Statement No. 33-46165.

E5

- 
- 10.49 Form of 1993 Non-Employee Director Stock Option Plan, incorporated by reference to exhibit 10.32 filed in connection with the Company's Annual Report on Form 10-K for the year ended December 31, 1992.
  - 10.50 Employment agreement, dated as of October 1, 2003, by and between Wayne T. Hockmeyer, Ph.D. and MedImmune, Inc.\*10.50
  - 10.51 Employment agreement between Edward J. Arcuri, Ph.D. and MedImmune, Inc. dated February 25, 2002, incorporated by reference to exhibit 10.133 filed with the Company's Annual Report on Form 10-K for December 31, 2001.
  - 10.52 Employment Agreement between David M. Mott and the Company dated August 15, 2002, incorporated by reference to exhibit 10.189 filed with the Company's Annual Report on Form 10-K for December 31, 2002.
  - 10.53 Part-Time Employment Agreement between Melvin D. Booth and the Company dated December 31, 2003.\*
  - 10.54 Employment Agreement between James F. Young and the Company dated August 15, 2002 incorporated by reference to exhibit 10.191 filed with the Company's Annual Report on Form 10-K for December 31, 2002.
  - 10.55 Employment Agreement between Armando Anido and the Company dated August 15, 2002 incorporated by reference to exhibit 10.192 filed with the Company's Annual Report on Form 10-K for December 31, 2002.
  - 10.56 Employment Agreement between Edward M. Connor and the Company dated August 15, 2002 incorporated by reference to exhibit 10.193 filed with the Company's Annual Report on Form 10-K for December 31, 2002.
  - 10.57 Employment Agreement between Gail M. Folena-Wasserman and the Company dated August 15, 2002 incorporated by reference to exhibit 10.194 filed with the Company's Annual Report on Form 10-K for December 31, 2002.
  - 10.58 Agreement and General Release between Gregory S. Patrick and the Company dated December 31, 2003.\*
  - 18.1 Independent Accountant's Preferability Letter Regarding a Change in Accounting Principle, incorporated by reference to exhibit 18.1 filed with the Company's Quarterly Report on Form 10-Q for the Quarter ended March 31, 2002.
  - 21 Subsidiaries of MedImmune, Inc.\*
  - 23.1 Consent of PricewaterhouseCoopers LLP\*
  - 31.1 Certification pursuant to 18 United States C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
  - 31.2 Certification pursuant to 18 United States C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
  - 32.1

Edgar Filing: MEDIMMUNE INC /DE - Form 10-K

Certification pursuant to 18 United States C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

99.1 Patent Table\*

---

Notes:

\*

Filed herewith.

(1)

Confidential treatment has been granted by the SEC. The copy filed as an exhibit omits the information subject to the confidentiality grant.

(2)

Confidential treatment has been requested. The copy filed as an exhibit omits the information subject to the confidentiality request.

E6

---